IMPLEMENTING MENTAL HEALTH SCREENING ASSESSMENT AND NAVIGATION (MH-SCAN) IN A COMMUNITY ONCOLOGY CLINIC: EVALUATIONS AND EFFICACY

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DEDICATION

I would like to thank the members of my Graduate Committee. In particular I would like to recognize Robrina Walker, Ph.D. for chairing the committee and providing invaluable input and guidance throughout this project. I would also like to thank Laura Howe-Martin, Ph.D. for allowing me the opportunity to complete this study, supervising me at UTSW MCI, and assisting in the implementation of the MH-SCAN program. Lastly, I would like to thank clinic and support staff at UTSW MCI for their support in implementation of the MH-SCAN program. Without any of you this project would not have been able to go forward.

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by

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Significant portions of cancer patients are attempting to manage the stressors of survivorship with undiagnosed depression. Untreated depression increases mortality rates, deteriorates patients' quality of life, and disrupts adherence to cancer treatment. Despite widespread recommendations, there remains a significant gap in identification of depression and engagement in depression treatment. To fill this gap, the University of Texas Southwestern Moncrief Cancer Institute implemented Mental Health Screening, Assessment, and Navigation (MH-SCAN) as standard of care. This study evaluated factors associated with screening positive for depression, as well as the impact of Mental Health Patient Navigation on depression treatment engagement and depression symptom reduction.

Universal, tablet-based screening using the Patient Health Questionnaire (PHQ-2, PHQ-9) was implemented to screen for depressive symptoms. After screening positive, a patient navigator contacted the patient to engage them in navigation services. For the current study, patients (N=500) diagnosed with cancer two years prior to PHQ-2 screening were selected for inclusion. Clinical and demographic data were collected via electronic health record review to compare patients based on positive (n=173) and negative (n=327) depression screening result.

Patients who were (n=106) and were not (n=67) navigated were then compared on their engagement in depression treatment and symptom reduction.

Approximately one-third of all patients screened positive for depression. Individuals, who had a pre-existing mental illness, are unmarried, have less education, are on disability, and earn \$30,000-\$40,000 per year (i.e., the "working poor") were significantly more likely to screen positive for depression. Significantly more (χ^2 = 62.224, p < .001) patients initiated referred depression treatment who were navigated (67%) compared to patients unable to be navigated (6%). Furthermore, patients who were navigated had significantly greater reductions in depressive symptoms (M = -6.43, SD=6.63) compared to patients unable to be navigated (M = -1.46, N=3.87), N=30.91, N=0.001.

We conclude that Mental Health Patient Navigation successfully bridges the depression screening and treatment gap, fulfilling recent recommendations put forth by numerous psychoncology groups. Our MH-SCAN program can serve as the model for future iterations of screening and treatment programs, providing crucial psychosocial care to at-risk oncology populations whose mental health has often gone underserved.

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¹Selected for Oral Presentation as one of the best five innovative clinical interventions.

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LIST OF DEFINITIONS

ACS – American Cancer Society

APOS – American Psycho-Oncology Society

ASCO – American Society of Clinical Oncology

CAST-SR – Concise Associated Symptoms Tracking – Self Report Scale

CHRT – Concise Health Risk Scale

 $DSM\text{-}5-Diagnostic \ Statistics \ Manual-5^{th} \ Addition$

FIBSER – Frequency, Intensity, and Burden of Side Effects Rating

FPL – Federal Poverty Level

GAD-7 – Generalized Anxiety Disorder 7

HPA – Hypothalamic-pituitary-adrenal Axis

IOM – Institute of Medicine

LOCF – Last Observation Carried Forward

MH-SCAN – Mental Health Screening, Assessment and Navigation

MHPN – Mental Health Patient Navigation

MI – Motivational Interviewing

MINI – Mini International Neuropsychiatric Interview

NCCN – National Comprehensive Cancer Network

PAQ – Patient Adherence Questionnaire

PHQ-9 – Patient Health Questionnaire-9

POMS – Profile of Mood States

QOL – Quality of Life

SES – Socioeconomic Status

UTSW – University of Texas Southwestern

UTSW MCI – University of Texas Southwestern Moncrief Cancer Institute

 $VS^6-Vital Sign^6\\$

CHAPTER ONE Introduction

In the United States, as well as worldwide, cancer has become a major public health problem. Cancer is currently the second leading cause of death in developed nations and is expected to surpass heart disease as the leading cause of death worldwide in the next few years (Siegel, Miller, & Jemal, 2015). However, in the United States the mortality rate for cancer has already exceeded heart disease in 22 states as of 2014 (Heron & Anderson, 2016). In the U.S. it is estimated that there were over 1.5 million new cases of cancer in 2015, the equivalent of 4,500 new diagnoses daily (Siegel et al., 2015). However, one aspect that is often overlooked in these statistics are the psychosocial implications this population faces. In clinics serving an oncology population the clinical "rule of thumb" is that 25% of cancer patients are likely depressed at some point (Massie, 2004). In fact, a meta-analysis of 58 studies conducted from 1980 to 1994 indicated cancer patients were significantly more depressed than the normal population (Massie, 2004). Furthermore, research indicates depression and anxiety in cancer patients is associated with poor health-related quality of life (Fann et al., 2008; Stark et al., 2002), and, more importantly, increased mortality rates (Buccheri, 1998; Hjerl et al., 2003; Pirl et al., 2012; Quinten et al., 2009). The occurrence of depression and other psychopathologies is significant within the oncology population, yet challenges remain for the assessment and treatment of mental health disorders. Competent treatment of depression must be a priority to the leaders who set up systems of care for cancer patients.

In order to competently treat psychiatric disorders, providers must first effectively and systematically screen, assess, and diagnose patients. However, oncology staff are often not trained in completing psychiatric evaluations (Fisch, 2004; Kadan-Lottick, Vanderwerker, Block,

Zhang, & Prigerson, 2005). Oncologists are no more effective in recognizing depression than primary care physicians (Fallowfield, Ratcliffe, Jenkins, & Saul, 2001; Greenberg, 2002; Meredith, Wells, Kaplan, & Mazel, 1996; Passik, Dugan, McDonald, Rosenfeld, Theobald, & Edgerton, 1998; Valente, Saunders, & Cohen, 1993), both of whom often do not detect depression, prescribe an adequate treatment regimen, or follow-up adequately on patients' treatment once initiated (Meredith et al., 1996).

To facilitate the assessment and treatment of depression, an integrated model whereby screening is integrated into cancer treatment protocols is encouraged. This process reduces stigma and increases adherence to referred treatment (Greenberg, 2002). The National Comprehensive Cancer Network (NCCN) Guidelines for Management and Distress (Andersen et al., 2014; Stovall, Greenfield, & Hewitt, 2005) encourages collegial interaction between psychiatrists, psychologists, social workers, and pastoral care counselors, who will consult with each other and relay feedback to the oncology team (Andersen et al., 2014; Greenberg, 2002; Holland, 1997). With this in mind, the Institute of Medicine recommends that all cancer care include the provision of appropriate integrated psychosocial services provided by behavioral health practitioners (Adler & Page, 2008). However, identifying patients who need psychosocial services and then providing treatment to this population is complicated due to a shortage of behavioral health services and providers within oncology and medical settings in general (Burke et al., 2013).

Within most current models, the burden of screening, diagnosis, treatment, and follow up of psychopathology has been thrust upon other medical providers who typically lack significant behavioral health training. This puts a heavy burden on providers that do not have appropriate skills or support to adequately provide complex care or provide patients suitable treatment

referrals within the community. Unfortunately, within this paradigm, potentially half of the patients seen in oncology settings will go undiagnosed despite experiencing symptoms meeting criteria for a diagnosis of depression (Coyne, Schwenk, & Fechner-Bates, 1995; Harris et al., 2001). To fill this gap in the identification and treatment of depression in oncology clinics, there are now examples of varying integrative and collaborative care programs throughout the country (Adler & Page, 2008; Ell et al., 2011; Ell et al., 2008; Fann et al., 2009; Kroenke, Theobald, et al., 2010; Strong et al., 2008). Although research has sought to examine the efficacy of these programs, none of these studies have analyzed the whole screening, diagnosis, and treatment procedure (Thalén-Lindström, Larsson, Glimelius, & Johansson, 2013).

Moncrief Cancer Institute, an affiliate of UT Southwestern Harold C. Simmons

Comprehensive Cancer Center, instituted an integrated and collaborative approach to screening, patient navigation, and implementation of measurement-based care, known as Mental Health

Screening, Assessment, and Navigation (MH-SCAN) to the standard of care for its patients in

September 2015. The primary goal of the MH-SCAN program is to identify patients with depressive symptoms and to assist them in obtaining appropriate treatment services through the use of Mental Health Patient Navigation (MHPN). The ultimate goal of MH-SCAN is to mitigate the threat untreated depression poses to long-term physical health outcomes. This study will evaluate depression related outcomes, thereby laying the foundation for future research evaluating the efficacy of the program in decreasing long-term mortality rates. To that end, the specific aims of this study are as follows: (1) to determine what clinical and demographic characteristics differentiate patients diagnosed with cancer within two years of initial screening and meet the clinical threshold indicative of mild or greater depressive symptoms versus those that do not meet the clinical threshold; (2) to describe the clinical and demographic

characteristics of patients identified as having mild or greater depressive symptoms and are able to be navigated via MHPN compared to those that are not able to be navigated; (3) determine if MHPN increases patients' engagement to referred treatment for depression; and (4) examine whether those that are able to be navigated via MHPN show more significant reduction in symptom severity versus those who are not able to be navigated via MHPN.

CHAPTER TWO Review of Literature

IDENTIFICATION AND TREATMENT OF DEPRESSION IN ONCOLOGY SETTINGS: SHORTCOMINGS WITHIN THE CURRENT PARADIGM

In 2012 there were 14.1 million new cancer cases and an estimated 8.2 million deaths due to cancer worldwide (Torre et al., 2015). These numbers continue to escalate each year, and while daunting, the field has made significant improvements in survival over the past three decades for most cancer types (Siegel et al., 2015). As cancer survivorship has increasingly become the norm, increasing attention has been placed on the long-term impact of depression on these patients (Mitchell, 2010). However, without first understanding the current prevalence rates of cancer, the psychological implications cannot be fully understood.

General Prevalence Rates of Cancer

Data regarding the incidence and mortality of cancer lags three to four years behind due to the requisite time needed for data collection, compilation, quality control, and dissemination (Siegel et al., 2015). Each year the American Cancer Society (ACS) publishes estimates of new cancer cases and deaths predicted to occur in the United States. Siegel and colleagues used previous years' national statistics to model and predict the rates of cancer incidence, mortality, and survival. They estimated that, in 2015 alone, there would be 1,325,370 new cases of cancer in the U.S., or the equivalent of 4,500 new cancer diagnoses each day. For men, the models predict that colorectal, prostate, and lung cancers will account for around one-half of all cases, with prostate cancer accounting for one-quarter of new diagnoses. For women, the most commonly diagnosed cancers are predicted to be breast, lung, and colorectum, which together

are estimated to account for one-half of all cases in women. The ACS further proposes that 29% of all new cancers will be accounted for by breast cancer alone (Siegel et al., 2015).

While cancer incidence continues to rise in the United States (Potosky, Kessier, Gridley, Brown, & Horm, 1990; Potosky, Miller, Albertsen, & Kramer, 1995; Siegel et al., 2015), the mortality rate has decreased due to earlier diagnosis and improved treatments leading to notable improvements in survival since the 1980s. For example, the five-year survival rate for acute lymphocytic leukemia increased from 41% in the mid 1970s to 70% by 2010. The ACS estimates that the five year relative survival rate for all cancers is expected to increase by 19 percentage points among whites and 23 percentage points in blacks during 2015 (Siegel et al., 2015).

While improved survival rates are a desired outcome, research has demonstrated a corresponding increase in rates of depression and other psychopathologies, amounting to an estimated 2 million in the U.S. living with major depression and cancer at any time (Mitchell, 2010). It is well known that major depression significantly limits work productivity, quality of life, and life expectancy (Fried & Nesse, 2014) in healthy, non-cancer populations, and has been cited by the World Health Organization as the leading cause of disability worldwide (W.H.O., 2016). Similarly, depression and other forms of psychopathology have a negative impact on the quality of cancer patients' lives, their ability to function, and also complicates the course of the cancer treatment. These negative impacts apply not only during the period of initial cancer treatment but also in the long-term for survivors of cancer (Ell, Nishimoto, Morvay, Mantell, & Hamovitch, 1989; Pratt-Chapman, Simon, Patterson, Risendal, & Patierno, 2012). It has become evident that a confluence of factors now leads to more patients with cancer surviving longer while concurrently experiencing symptoms of untreated depression. This clearly illustrates the

need for identifying these patients, addressing their distress, and effectively treating the depression.

Complications in Identifying and Treating Depression in Cancer Patients

There are many complications that exist in identifying cancer patients who are experiencing depressive symptoms. These complications are highlighted when attempting to determine accurate and valid depression prevalence rates within a cancer population. Numerous studies have sought to estimate the prevalence of depression and other psychopathologies within a cancer population. However, published rates of depression in cancer patients vary widely due to differences between clinical and demographic characteristics of study populations (e.g., cancer site, length of time since diagnosis, course of disease and stage of treatment when screened, previous psychiatric history, age, sex), study criteria for defining the psychiatric disorder, and the validity of the screening tools (Massie, 2004). Thus, determining the prevalence rates of depression in cancer populations is challenging for a number of reasons; three of the most confounding are discussed further below.

First, there is great overlap between symptoms of various psychological disorders (e.g., Adjustment Disorder vs. Major Depressive Disorder), and more importantly, symptoms of the cancer itself or side effects of various cancer treatments. For example, depressive symptoms occur on a spectrum that ranges from sadness to a major depressive disorder, but mood and changes in mood are often difficult to evaluate when a patient is confronted by repeated threats to life due to their cancer (Massie, 2004). Furthermore, depressive symptoms overlap with symptoms of cancer and the sequelae of cancer treatments. Common side effects of cancer and its treatment such as fatigue, loss of appetite, and difficulties with concentration and attention are three of the nine DSM-5 specific symptom criteria for major depressive disorder. Therefore, the

differential diagnosis for depression can easily become blurred when attempting to differentiate between symptoms associated with a depressive disorder and symptoms more related to cancer or its treatment.

Second, prevalence rates have been difficult to ascertain because the majority of research has relied on either distress or depression screening rather than diagnostic instruments (Mitchell, 2010). While screening tools are useful due to their ease of implementation, low cost, and minimal inconvenience to clinic staff (Randall, Voth, Burnett, Bazhenova, & Bardwell, 2013), there are limitations in terms of diagnostic accuracy, leading to over or under pathologizing mental illness (Lamers et al., 2013; Loquai et al., 2013; Miovic & Block, 2007; Schaeffeler et al., 2009; Waller, Williams, Groff, Bultz, & Carlson, 2013). Structured or semi-structured diagnostic interviews, such as the Structured Clinical Interview for the DSM, are the gold standard and include a diagnostic algorithm, clinical significance criteria, and minimum duration to support a robust diagnosis. As such, the actual rates of depression within an oncology population are not clear (Mitchell, 2010).

Third, prevalence rates vary widely because those making the psychiatric diagnosis are most often oncologists who are not significantly trained in mental health and often find operational diagnoses and formal screening questionnaires burdensome (Mitchell, 2010). In fact, an NIH-funded study examining the prevalence of mental illness and patterns of mental health service utilization in advanced cancer patients identified that only 17% of patients in their sample had any type of discussion about mental health with their providers (Kadan-Lottick et al., 2005).

As described above, current standards for screening, diagnosing, and treating depression in cancer patients are insufficient. Survival rates of cancer are increasing, leading to a corresponding increase in cancer patients receiving cancer care while failing to have

psychological needs met. Providers are failing to recognize these at risk patients as experiencing mental illness due to lack of appropriate means for screening, as well as a lack of experience diagnosing psychopathology in general, and in particular within such a diagnostically complicated population. As such, the status quo in oncology is failing to identify and, consequently, provide care for theoretically large numbers of at risk patients who may potentially have a comorbid mental health problem. This standard of care has led to a significant gap in the identification and treatment of oncology patients with mental health disorders.

PSYCHOPATHOLOGY IN ONCOLOGY PATIENTS

Cancer is known to cause distress in patients afflicted with the disease. Many cancer patients are able to cope with distress effectively, with most (65%) terminally ill patients reporting minimal or no distress (Van Der Lee, Swarte, Van Der Bom, Van Den Bout, & Heintz, 2006). Yet there is a subset of this population that lacks effective coping tools and it is estimated up to 6-11% of patients have frequent suicidal thoughts (Leung et al., 2013; Rao et al., 2012; Spencer, Ray, Pirl, & Prigerson, 2012). Furthermore, some patients have pre-existing psychiatric disorders that are worsened due to the stress of advanced disease, whereas others who lack this pre-existing risk factor may develop new symptoms of depression during the course of their cancer (Miovic & Block, 2007).

Several factors contribute to psychological distress in the oncology population (Massie, 2004). First, receiving a cancer diagnosis elicits significant psychological reactions. Grief about current and anticipated loss, fear of death, and concerns about loved ones are related to depressive and anxious symptoms (Kadan-Lottick et al., 2005). Second, cancer treatments themselves have been found to be associated with side effects that produce symptoms of depression (Massie, 2004). For example, the side effects of certain chemotherapies are known to induce symptoms such as low energy, changes in appetite, anhedonia, and decreased sleep (Besisik, Kocabey, & Caliskan, 2003; Ito et al., 2003; Massie, 2004), and estrogen receptor-blocking medications have been known to induce significant mood symptoms (Koch et al., 2014). Third, the biology of the malignancy has been related to changes in mood, as it has been demonstrated that psychopathology can be linked to tumor-induced changes in neuroendocrine or acid-base systems related to the growth of pancreatic tumors (Green & Austin, 1993). Lastly, it must be noted that previous history of depression has been found to be one of the strongest

predictors for developing new or recurrences of depression in the face of new stressors (Jadoon, Munir, Shahzad, & Choudhry, 2010). In the following section, the prevalence rates, risk factors, and clinical presentation of depression are described in more detail.

Depression in Oncology Patients

Of all the possible mood disorders associated with cancer, depression has been the most extensively researched (Mitchell et al., 2011). It is defined as persistent low mood or anhedonia (pervasive loss of interest or pleasure), that lasts for two weeks or more and is accompanied by at least three of the seven following symptoms: sleep disruption, weight loss or change in appetite, psychomotor retardation or agitation, fatigue or loss of energy, feelings of worthlessness or guilt, diminished ability to think or concentrate, and recurrent thoughts of death or suicidal ideation (A.P.A, 2013). However, because many of the physical symptoms of depression (e.g., low energy, psychomotor agitation, sleep disturbances, changes in appetite) are associated with cancer in and of itself, as well as side effects of certain cancer treatment, various clinicians propose operationalizing the diagnosis in a unique way for this population (Potash & Breitbart, 2002). With research identifying the bidirectional relationship between fatigue and depression in cancer patients (Barsevick, Dudley, & Beck, 2006), as well as findings that inflammatory cytokines may cause both depression and the cancer "sickness syndrome" (Illman et al., 2005; Raison & Miller, 2003), it is proposed that the best practice is to include all neurovegitative symptoms. This is so that all symptoms that may have their etiology from the side effects of cancer treatments be included as signs of depression in patients with cancer and advanced disease (Miovic & Block, 2007).

Prevalence

The 30-day prevalence for Major Depressive Disorder in general community samples is approximately 5% with an incidence of approximately 9% over 12 months (McDowell et al., 2004). However, depression is known to be a substantial complication in patients with cancer, and its prevalence is higher in oncology patients than in the general population (Dalton, Laursen, Ross, Mortensen, & Johansen, 2009; Härter et al., 2007; Honda & Goodwin, 2004). The prevalence of depression in oncology patients ranges widely from 3 to 38% (Akechi et al., 2004; Breitbart et al., 2000; Chochinov, Wilson, Enns, & Mowchun, 1995; Colón, Callies, Popkin, & McGlave, 1991; Jenkins, May, & Hughes, 1991; Krebber et al., 2014; Maguire, Walsh, Jeacock, & Kingston, 1999; Power et al., 1993). Due to this wide variance, meta-analyses are helpful in gaining a clearer picture of these rates. A meta-analysis conducted by Mitchell and colleagues (Mitchell et al., 2011) identified 433 relevant articles on the prevalence of various psychopathologies in oncology populations. Of these 433 articles, they analyzed 369 that included patients with cancer who were assessed with an interview-based diagnostic method, versus screening methods alone. Results of their meta-analysis revealed that the prevalence for depression ranged from 5.1% to 30.1% in the individual studies, with a pooled prevalence of major depressive disorder of 14.1% (Mitchell et al., 2011). Despite the varied reports of prevalence, rates ranging up to 30% highlights a wide chasm between the observed prevalence of depressive disorders in an oncology population versus the general population.

Proposed Causes of Variance in Prevalence Rates

Depression has been challenging to study. Massie and colleagues (2002) noted that the "reported prevalence varies significantly because of varying conceptualizations of depression, different criteria used to define depression, differences in methodological approaches to the measurement of depression, and different populations studied and different times in the disease course (i.e., hospitalized patients post-surgery; patients awaiting bone-marrow transplants; patients without evidence of disease and likely cured, evaluated at annual oncology clinic follow-up or screening visits; different cancer sites)". Further complicating this research is the finding that prevalence rates may change in relation to the time course of the cancer. There is a higher prevalence of depression during the acute (initial diagnosis and treatment) phase of the disease whereas anxiety becomes more common in later phases (Krebber et al., 2014).

Risk factors for and clinical presentation of depression in cancer patients

Numerous risk factors predispose cancer patients to the development of depression including cancer type, previous history of depression, younger age, decreased social support, and decreased physical functioning associated with the cancer. Cancer types highly associated with depression are oropharyngeal (22-57%), pancreatic (33-50%), breast (4.5-46%), and lung (11-44%) (Massie, 2004). A clinical history of depression or bipolar disorder is likely the most significant risk factor for current major depression in patients with advanced cancer (Chochinov, Wilson, Enns, & Lander, 1997; Kadan-Lottick et al., 2005; Lloyd-Williams, Dennis, Taylor, & Baker, 2003). Other risk factors include younger age, poor social support network, poor functional status, and pain (Potash & Breitbart, 2002). A person's perception of the cause of their cancer, such as self-devaluative cognitions (Teasdale & Cox, 2001), may also affect their

vulnerability for depression (Jadoon et al., 2010). Furthermore, complications associated with cancer such as hypothyroidism, hyperthyroidism, anemia, and various cancer treatments such as corticosteroids and certain chemotherapeutic drugs (e.g., tamoxifen and interferon) can also prompt depressive symptoms (Mainio et al., 2005; Pirl et al., 2012; Potash & Breitbart, 2002; Skarstein, Bjelland, Dahl, Laading, & Fosså, 2005). Providers should be familiar with these risk factors when assessing for depressive symptoms in cancer patients. They must understand types of cancer associated with increased risk for mental illness, look for the cardinal signs and symptoms listed previously, as well as inquire as to any personal or family history of depression given its role as a key risk factor (Chochinov et al., 1997; Lloyd-Williams et al., 2003).

Other common signs and symptoms of depression in cancer patients include irritability, social withdrawal, body aches, lowered pain tolerance, tearfulness, and feelings of hopelessness or helplessness (Miovic & Block, 2007). Further assessment includes probing for how the patient sees the future and how much they believe they can influence their care, both of which have been shown to assist in identification of depressive disorders. Finally, it is also helpful to obtain collateral information from the patient's family or caregivers about their behavior and mood. In regards to a patient's risk for self-harm, research has shown that normalizing the occurrence of suicidal thoughts in advanced disease gives patients permission to be more forthcoming about suicidal thoughts or plans (Potash & Breitbart, 2002).

For patients in more advanced phases of disease, providers often must differentiate between symptoms of anticipatory grief and major depression. Grief and depression are associated with somatic distress and social withdrawal, both of which are strong signs of depressive pathology (Block, 2006). Patients who are grieving present with waxing and waning sadness that is distinctly connected with loss of functioning or identity, and they may have

passive suicidal ideation but nonetheless are able to look forward to the future and exhibit positive self-worth. However, patients that are likely to have a diagnosable depressive disorder present with pervasive anhedonia, are unable to see pleasure in their future, and may have more active suicidal thoughts, as well as low self-worth (Block, 2006).

The development of depression in an oncology population is a both a complicated and common occurrence. While it is important to understand the clinical presentation and risk factors associated with major depressive disorder, we will now turn our attention to the consequences posed to cancer patients if the disorder goes undiagnosed.

CONSEQUENCES OF UNTREATED DEPRESSION IN ONCOLOGY PATIENTS

Having discussed the prevalence and risk factors associated with the development of depression in cancer patients, we must now turn to why identification and treatment of mental disease is so vital to the holistic and comprehensive approach to cancer care. In cancer settings, evidence shows that psychopathology causes serious suffering and distress, reduces participation with medical care, and potentially prolongs patients' length of stay during hospital admission (Bui, Ostir, Kuo, Freeman, & Goodwin, 2005; Colleoni et al., 2000). Whether a patient suffers with depression, anxiety, or another disorder, each impacts the quality of patients' lives and their ability to function. This impact applies not only during the period of initial cancer treatment but also in the long term for survivors of cancer (Ell et al., 1989; Pratt-Chapman et al., 2012), as their consequences are seen in reductions in quality of life (Bui et al., 2005; Pinquart & Duberstein, 2010), interference with rapport between patient and provider (Goold & Lipkin, 1999; Seetharamu, Iqbal, & Weiner, 2007), and increased mortality rates (Buccheri, 1998; Pirl et al., 2012).

Poor Quality of life

As cancer treatments have improved over the years, there has been increasing emphasis on the importance of not only the short-term, but the long-term implications of care. As such, the term quality of life has become common in the lexicon of oncology providers. Quality of life (QOL) relates not only to the impact of treatment and its side effects, but also to the acknowledgment of viewing the patient as an "individual, and as a whole person, body, mind and spirit" (Calman, 1984). An individual's quality of life includes all areas of life and experience and takes into account the impact of illness and treatment (Calman, 1984). Depression and other

forms of psychopathology negatively impact cancer patients' QOL, leading to consequences in numerous domains.

Untreated depression is associated with amplified pain (Passik, Dugan, McDonald, Rosenfeld, Theobald, & Egerton, 1998), which is a major contributor to diminished QOL. Poor quality of life negatively affects both psychological and physical health, and also may undermine interpersonal relationships with family, friends, and health care providers (Bambauer et al., 2006; Bjelland, Dahl, Haug, & Neckelmann, 2002). Not only does this create a vicious cycle leading to further psychological distress, it also leads to negative health consequences (Block, 2000; Breitbart et al., 2000; Passik, Dugan, McDonald, Rosenfeld, Theobald, & Egerton, 1998; Quinten et al., 2009). In fact, poor quality of life has been related to poor survival (Quinten et al., 2009), increased desire for hastened death (Breitbart et al., 2000), impaired ability to participate in end of life planning (Block, 2006), and diminished psychological functioning of care givers (Bjelland et al., 2002). As patients face increased emotional distress, they tend to engage in avoidance and distraction as they attempt to cope with negative affect. This continues the cycle, as it isolates one from others, makes it harder to manage the inevitable painful emotions that accompany serious disease and difficult treatments, and makes it difficult to engage in additional means of coping (Spiegel, 2001). However, by identifying and treating depression in cancer patients, quality of life has been found to improve, mitigating these risks (Spiegel, 2001).

Impaired Patient-Provider Relationship

In all interactions between patient and health care professional, trust and rapport is paramount as it is a prerequisite for reducing patients' anxiety, enabling them to regain a sense of control (Rortveit et al., 2015), which encourages increased self-care behavior (Gupta et al., 2014).

This is especially true in oncology settings. Within oncology, a trusting patient-physician relationship may help reduce shame, humiliation, and power imbalances. These reductions have been observed to increase the patient's perception that the physician acknowledges and appreciates their pain, leading to better treatment satisfaction and adherence (Hillen, de Haes, & Smets, 2011; Seetharamu et al., 2007; Spencer, Nilsson, Wright, Pirl, & Prigerson, 2010).

Spencer and colleagues (2010) explored associations between mental illness and cancer patients' physical performance status, patient-physician relationships, end of life treatment preferences and outcomes, and quality of death. They observed that patients with anxiety disorders are significantly less likely to trust their physicians, believe that treatments offered to them were often futile, and less likely to understand their treatment options (Spencer et al., 2010). This causes a sense of distrust in the provider, and in turn profoundly impacts a patient's willingness to accept and adhere to the advice and treatment recommendations of the physician (Freedman, 2003), reduced acceptance of medication (Reid, Gooberman-Hill, & Hanks, 2008), and increased refusal of recommendations for further diagnosis or treatment (Sharf, Stelljes, & Gordon, 2005), all of which negatively impact treatment outcomes.

Negative Treatment Outcomes

As discussed previously, negative quality of life and impaired rapport result in negative consequences that can impact treatment outcomes. Therefore, major depression may be associated with shorter survival time in some cancer patients (Stommel, Given, & Given, 2002), especially hematological cancers after stem-cell transplantation and low-grade gliomas (Loberiza et al., 2002; Mainio et al., 2005). In fact, and perhaps surprisingly, the negative effect of depression on mortality rates is predominantly seen among patients with early-stage cancer (Sullivan et al., 2016). Furthermore, depression is a major risk factor for desire to hasten death

(Chochinov et al., 1997; Lloyd-Williams et al., 2003; O'Mahony et al., 2005), and as many as 59% of terminally ill patients who request assisted suicide have major depressive disorder (Emanuel, Fairclough, & Emanuel, 2000).

Randomized trials indicate psychosocial support is associated with longer survival for patients with breast cancer, malignant melanoma, and lymphoma (Fawzy, Fawzy, Arndt, & Pasnau, 1995; Richardson, Shelton, Krailo, & Levine, 1990; Spiegel, Kraemer, Bloom, & Gottheil, 1989). It is proposed that this may be due to a meaningful link between endocrine function and cancer (Spiegel & Giese-Davis, 2003), as an association between stress-related cortisol and the stimulation of more rapid tumor growth has been identified (Zhao et al., 2000). This has implications for the impact of depression on cancer related outcomes due to the relationship between depression, anxiety, and other forms of emotional distress in their neuroendocrine effects (Heim et al., 2000; Levine, Lyons, & Schatzberg, 1997; Nemeroff et al., 1984; Ramirez et al., 1989; Yehuda et al., 1993).

Repeated and sustained activation of the hypothalamic-pituitary-adrenal (HPA) axis can result in a system that is hyperactive, leading to elevated cortisol levels and loss of diurnal variation, or to a hyperactive system that fails to respond to normal activating signals (Mcewen, 2014). In cancer patients, the more a patient perceives being supported by their environment, the lower their morning cortisol levels (Turner-Cobb, Sephton, Koopman, Blake-Mortimer, & Spiegel, 2000). Research has confirmed this link between social support and cortisol levels in cancer patients by demonstrating that group support for breast cancer patients reduces mean levels of cortisol (Cruess et al., 2000). As such, untreated depression can have a very direct effect on cancer outcomes, remission rates, and survival. In fact, there is a 30% higher fatality rate from

cancer in patients with major psychiatric conditions despite the incidence of cancer being no greater than in the general population (Kisely, Crowe, & Lawrence, 2013).

TREATING DEPRESSION IN ONCOLOGY PATIENTS

The numerous negative consequences associated with untreated depression in oncology patients can be mitigated if patients can be identified and referred to treatment. Given this, there is growing recognition that psychosocial treatment is an essential component of comprehensive care for people afflicted with cancer (I.O.M., 2004). The primary goal of psychological care is to decrease emotional distress and promote wellness, goals that are key to improving the quality of patients' lives (Jacobsen & Jim, 2008).

In recent years, numerous organizations have put forth clinical practice recommendations for the management of depression in cancer patients. The National Comprehensive Cancer Network (NCCN), which includes 21 major cancer centers in the United States, has developed several clinical practice guidelines for the supportive care of these individuals. The NCCN Guidelines for Distress Management, first released in 1999 (N.C.C.N., 1999) and updated annually, proposes evidence-based recommendations for evaluation, treatment, and follow-up care. Most recently the American Society of Clinical Oncology (ASCO) has taken steps to address suggestions from the NCCN as well as the call by the Institute of Medicine for the "use of systematically developed evidence-based clinical practice guidelines, assessment tools, and screening instruments" (Hewitt, Greenfield, & Stovall, 2005) to help identify and manage psychological effects of cancer and its treatment (Andersen, Rowland, & Somerfield, 2015).

For patients with a mood disorder, the initial recommendation by ASCO is for evaluation, diagnostic studies to rule out physiologic causes of changes in mood, and modification of psychosocial factors contributing to mood symptoms. Recommendations include initiation of psychotropic medication, psychotherapy, and consideration of referral to social work or other

treatment services while also initiating follow-up to assess for treatment adherence and symptom reduction (Andersen et al., 2015; Jacobsen & Jim, 2008; 1999).

Evidence-based Treatment for Depression in Oncology Patients

In regards to types of services to refer patients, in 2005 the National Breast Cancer Center and the National Cancer Control Initiative in Australia published the first edition of *Clinical Practice Guidelines for the Psychosocial Care of Adults with Cancer* (Turner et al., 2005). These guidelines indicate that cognitive behavioral and psychoeducational interventions are among several effective modalities in the treatment of depression. However, very few studies in medically ill populations have described the effect of psychotherapy with sufficient methodological detail (Stiefel, Die Trill, Berney, Nunez Olatre, & Razavi, 2001). Several meta-analyses and controlled trials of psychological interventions for decreasing emotional distress in patients with cancer have been published (Devine & Westlake, 1995; Faller et al., 2013; Jacobsen & Jim, 2008; Meyer & Mark, 1995; Newell, Sanson-Fisher, & Savolainen, 2002; Sheard & Maguire, 1999).

In a meta-analysis Sheard and Maguire reported the results of 20 trials, comprising 1023 participants, finding a combined effect size of 0.42 when analyzing the effect of various psychosocial interventions on reduction of anxiety related symptoms as measured by the Profile of Mood States (POMS) anxiety subscale as well as the Spielberger State Anxiety Inventory and others (Sheard & Maguire, 1999). This same meta-analysis explored the efficacy of psychosocial interventions on depressive symptoms as well, finding a combined effect size of .36 in a total sample of 1101 participants spanning 20 trials using the POMS depression subscale and Beck Depression Inventory to assess symptom severity post intervention (Sheard & Maguire, 1999).

More recently, Faller and colleagues (Faller et al., 2013) performed a comprehensive systematic review and meta-analysis covering the largest number of randomized controlled studies to date, with the purpose of revealing whether psychosocial interventions for adult patients with cancer decrease emotional distress and improve quality of life. They examined the efficacy of psychosocial interventions such as psychoeducation, coping skills training, psychotherapy, and relaxation training. Using only randomized controlled trials, they included only studies using primary outcomes of emotional distress, health related quality of life, and anxiety and depressive symptoms post treatment. In their analysis of individual psychotherapy, they identified 55 studies that included 6,820 participants and found a significant medium effect on emotional distress, anxiety, depression, and quality of life post-treatment (Faller et al., 2013). While examining the efficacy of couples therapy, they identified 10 trials involving 1,115 patients and found a small but significant effect on emotional distress. Forty-six trials, including 3,115 patients, were used in examining relaxation training and were subsequently found to have a significant small to medium effect on emotional distress, anxiety, depression, and quality of life. Lastly, they included 19 studies involving 3,857 patients in analyzing the effects of psychoeducation. This intervention was found to have a significant small effect on emotional distress, anxiety, depression, and quality of life post-treatment.

As is evident, there are various evidence-based psychosocial treatments that have significant effects on the reduction of depression in an oncology population. This evidence must be translated into evidence-based recommendations that are applicable to clinical practice (Jacobsen & Kadlubek, 2010). Jacobsen and colleagues accepted this challenge and put forth a listing comprised only of studies with a significant (p < .05) effect for a specific an intervention (Jacobsen & Kadlubek, 2010). Using this approach, psychoeducation (McQuellon et al., 1998),

problem-solving therapy (Nezu, Nezu, Felgoise, McClure, & Houts, 2003), stress management training (P. B. Jacobsen et al., 2002), individual cognitive behavioral therapy (Savard et al., 2006; Savard, Simard, Ivers, & Morin, 2005), and group cognitive behavioral therapy (Simpson, Carlson, & Trew, 2001) have been recommended for use as evidence-based practice for treating depression in an oncology population (Jacobsen & Kadlubek, 2010).

Thus, there are treatment modalities with proven efficacy that can reduce emotional distress in cancer patients and, therefore, improve quality of life and treatment outcomes. However, there remains a significant gap in providing treatment despite repeated guidelines advocating for its inclusion as part of comprehensive care. Problems with adherence to referred care are not unique to cancer patients, as only 59.6% of patients with a serious mental illness within the general population, report receiving psychiatric treatment (Corrigan et al., 2014; SAMHSA, 2012). With recommendations from the NCCN and ASCO suggesting continual follow-up for treatment adherence with referred care, as well as to monitor symptom reduction, patient navigation associated with screening may prove to bridge this gap and fulfill proposed recommendations for comprehensive cancer care.

SCREENING, TREATMENT, AND FOLLOW-UP: THE ROLE OF PATIENT NAVIGATION

In recent years, there has been a growing consensus in support of the need for universal and routine distress screening for cancer patients (Mitchell et al., 2011). Beginning in 1999 with the NCCN's Guidelines for Distress Management, there have been continued suggestions for the inclusion of distress screenings put forth by the NCCN and other oncology and psychoncology groups such as the American Psycho-Oncology Society (APOS) and the American Society for Clinical Oncology (ASCO) (Andersen et al., 2015; Holland, Watson, & Dunn, 2011; N.C.C.N., 1999, 2012). In 2005, the IOM went so far as to propose that distress be considered the "sixth vital sign" (I.O.M., 2005). They recommended that regular screening for distress be one component of a comprehensive process delivering whole-patient care, through the integration of both psychosocial and biomedical cancer services (I.O.M., 2005). In fact, recent guidelines by ASCO (Andersen et al., 2015) recommend "all patients with cancer/cancer survivors be evaluated for symptoms of depression and anxiety at periodic times across the trajectory of care." These guidelines go on to reinforce the importance of identifying available and accessible supportive care services, as well as reassessing patients' adherence with referrals for mental health services and treatment outcomes. However, the progress in implementation of the guidelines proposed by The National Comprehensive Cancer Network and others has been modest at best.

Jacobsen and colleagues (Jacobsen et al., 2011) studied 15 of the NCCN member institutions in 2005 to evaluate the implementation of the NCCN Guidelines for Distress Management. Their evaluation found that only eight of the 15 (53%) performed universal distress screenings with an additional four (27%) institutions implementing pilot screening

strategies in the eight years since the NCCN's original recommendations were released. In fact, they concluded that only 20% of NCCN member institutions screened all patients as the guidelines recommended. In 2012, the NCCN Distress Management Panel completed a similar survey to compare growth of implementation since 2005. During the passing seven years, the survey revealed only a 7% increase in institutions conducting routine screenings (Donovan & Jacobsen, 2013). Thus, simply implementing screening procedures has proven difficult, and yet there remain even more significant barriers in providing treatment to patients experiencing depression. This is illustrated in the study by Kaden-Lottick and colleagues (2005) in which only 28% of patients were able to access mental health services, including only 45% of patients with a diagnosed psychiatric disorder, despite 90% of patients reporting a desire to engage in mental health services if they were aware they had emotional problems (Kadan-Lottick, Vanderwerker, Block, Zhang, & Prigerson, 2005). As such, screening and referring to care as the guidelines currently recommend appear insufficient to meet patients' needs. A further step must be included in the screening and treatment process. This step involves accurate identification of depression in at risk patients, overcoming treatment barriers, referring to appropriate care, and managing conflicts associated with non-adherence to referred care as a means of filling the treatment gap.

To address these challenges, the American Psychosocial Oncology Society and the Yale School of Nursing proposed five steps for psychosocial distress management including: (1) screening, (2) evaluating, (3) referring, (4) following up, and (5) documenting and quality improvement (Lazenby, Tan, Pasacreta, Ercolano, & McCorkle, 2015). They suggest a structured triage system in which patients who have been identified as having moderate to severe levels of distress are supplied appropriate referrals within a set time frame (Estes & Karten, 2014; Lazenby et al., 2015), due to the evidence suggesting that screening in the absence of such

triage does not improve patient outcome (Hollingworth et al., 2013). This model also suggests that a successful program of comprehensive psychosocial distress screening also include providing follow-up with the patient to (1) evaluate adherence with referred treatment and to (2) re-evaluate distress to determine need for additional referrals to augment or modify the current intervention (Lazenby et al., 2015; N.C.C.N., 2012). Perhaps the most efficient way to fulfill the recommended guidelines of APOS, ASCO, NCCN and others is to couple "Mental Health Patient Navigation" (MHPN) and measurement-based care into oncology distress screening programs.

Patient Navigation: Its Evolution and Purpose in Cancer Care

Beginning in 1989, it was found that the most at risk people for being identified with advanced stage malignancies at cancer diagnosis, as well as high mortality, include racial/ethnic minorities and socioeconomically disadvantaged populations who were more likely to be uninsured (C.W.F., 2006). Soon, a growing body of literature began to reveal barriers to accessing care once a cancer screening abnormality had been identified (Friedman et al., 1995; Haas, Phillips, Sonneborn, McCulloch, & Liang, 2002; Hughes, Lerman, & Lustbader, 1996; Lannin et al., 1998; McCarthy et al., 1996; Perez-Stable, Sabogal, Otero-Sabogal, Hiatt, & McPhee, 1992; Roetzheim et al., 1999; Rojas, Mandelblatt, Cagney, Kerner, & Freeman, 1996; Royak-Schaler et al., 1995; Woloshin, Schwartz, Katz, & Welch, 1997). To understand the unique barriers faced by these "at risk" populations in accessing the often complex systems needed for appropriate cancer care, the American Cancer Society (ACS) conducted a series of hearings in 1989 with low-income Americans throughout the United States (Wells et al., 2008). The ACS published *Report to the Nation: Cancer in the Poor* (A.C.S., 1989), which indicated that poor individuals' access to services were impeded by: (1) widespread financial barriers, such

as being unable to afford health insurance, Medicaid or Medicare ineligibility, losing employment that provides health insurance, and lack of affordable cancer services; (2) logistical barriers, such as lack of transportation, living at a geographic distance far from healthcare, lack of appointment reminder systems, and lack of understandable cancer information; and (3) sociocultural barriers, such as limited social support and inadequate health literacy (A.C.S., 1989).

Following the release of this ACS report, in 1990 Dr. Harold P. Freeman began collaborating with the ACS to create the first patient navigation program in Harlem, New York, focusing their efforts on women with historically poor breast cancer outcomes (Freeman, 2006; Freeman & Chu, 2005; Newman-Horm, 2005). The program assisted low-income women in overcoming barriers to breast cancer screening and follow-up care, as well as sought to provide patient navigation services to women who had a clinical finding of suspicious cancer (Freeman & Chu, 2005). Due to the improvement in both adherence to follow-up and in the timeliness of obtaining care from screening abnormality to diagnostic resolution among patients, patient navigation programs have become more widespread and commonplace among community cancer centers (Ko et al., 2014).

Defining patient navigation

There are varying definitions of patient navigation (Fowler, Steakley, Garcia, Kwok, & Bennett, 2006; Freeman, 2006; Newman-Horm, 2005; Scotia, 2004), it has generally been described as a barrier-focused intervention that has the following common characteristics: (1) it is provided to individual patients for a defined episode of care; (2) it has a definite endpoint in which services are complete; (3) it targets a defined set of health services that are required to

complete care; (4) navigation services focus on identification of individual patient-level barriers to accessing care; and (5) it aims to reduce delays in accessing the continuum of cancer care services, with an emphasis on timeliness of diagnosis and treatment and a reduction in the number of patients lost to follow-up (Wells et al., 2008).

Despite its narrow barrier-focused definition, patient navigation has been operationalized quite broadly in practice. The term "navigator" has been applied to any type of service that assists individuals in overcoming obstacles during the continuum from screening to treatment and in coping with challenges of survivorship (Wells et al., 2008). Four areas in which Patient Navigators typically intervene include: (1) overcoming health system barriers; (2) providing health education about cancer across the cancer continuum from prevention to treatment; (3) addressing patient barriers to cancer care; and (4) providing psychosocial support (Wells et al., 2008).

To overcome health system barriers, Patient Navigators may coordinate care from multiple providers; assist patients with completing paperwork; schedule, confirm, reschedule, and attend appointments; and facilitate patient-provider communication (Battaglia, Roloff, Posner, & Freund, 2007; Bruce, 2007; Fillion et al., 2006; Jandorf, Gutierrez, Lopez, Christie, & Itzkowitz, 2005; N.C.I, 2005; Nash, Azeez, Vlahov, & Schori, 2006; Nguyen et al., 2006; Petereit et al., 2005; Rahm, Sukhanova, Ellis, & Mouchawar, 2007; Seek & Hogle, 2007; Steinberg et al., 2006). When providing health education, Patient Navigators provide written information, discuss diagnostic and genetic tests, discuss treatment options, and answer patients' questions (Bruce, 2007; Fillion et al., 2006; Petereit et al., 2005; Rahm et al., 2007; Rogers & Petereit, 2005; Seek & Hogle, 2007; Steinberg et al., 2006; Wilcox, 2007). To overcome patient barriers to cancer care, a Patient Navigator may address issues such as lack of transportation,

financial and insurance barriers, lack of childcare, language translation, low health literacy, or low literacy (Burhansstipanov et al., 1998; Frelix, Rosenblatt, Solomon, & Vikram, 1999; Giese-Davis et al., 2006; N.C.I, 2005; Petereit et al., 2005; Rogers & Petereit, 2005; Steinberg et al., 2006). Patient Navigators also provide psychosocial support or emotional support, either directly or by referring patients to social workers or cancer support groups (Burhansstipanov et al., 1998).

Mental Health Patient Navigation

While there is no single solution to resolving and overcoming barriers inherent in the complex U.S. healthcare system, patient navigation for cancer treatment has shown significant promise in reducing delays to diagnosis and treatment initiation (Gabram et al., 2008; Wells et al., 2008). Because these same barriers impede access to mental health care (Fann, Ell, & Sharpe, 2012), it may be in its ability to traverse these barriers that Mental Health Patient Navigation (MHPN) may prove useful. Although there are currently no published accounts of MHPN in oncology, Dr. Harold Freeman (the aforementioned founder of the concept of patient navigation) and others have recognized the opportunity and need to extend the practice of general oncology patient navigation to the survivorship period due to the physical, psychosocial, and emotional needs of an ever increasing number of cancer survivors (Pratt-Chapman et al., 2012). By using the oncology patient navigation model, MHPN may improve care by concretely facilitating communication between patient and provider, identifying psychosocial barriers to mental health care, providing emotional support, and linking patients to appropriate mental health resources. Furthermore, these and other duties of patient navigation may decrease the internal and external stigma that is often a barrier to seeking mental health care and adhering to appropriate behavioral health referrals.

Defining Stigma and its Interference on Treatment Adherence

Once a patient is identified as experiencing depressive symptoms, it is imperative that they enter into appropriate treatment. In order to achieve this aim, stigma, known to be a significant barrier to receiving mental health care (Corrigan, 2013), must be overcome. Stigma is defined as a characteristic or quality that disparages and degrades an individual who possess the characteristic (CDC, 2015; Goffman, 2009). It involves the co-occurrence of its components—labeling, stereotyping, separation, status loss, and discrimination (Link & Phelan, 2001). Each of these components will be explored to better understand the phenomenon of stigma.

Labels, which are negative in nature, are used to distinguish individuals afflicted by the stigma as being in "an out group." These labels often come in the form of stereotypes meant to separate "them" (the stigmatized) from "us" (the non-stigmatized). As a result of this separation, the "out group" experiences loss of status, discrimination, and prejudice (Link & Phelan, 2001). These stereotypes, prejudices, and the resulting discrimination leads to both public and private internalizations of stigma, each of which have negative effects on care seeking and treatment adherence. When a person internalizes these stereotypes out of fear of being discriminated or experiencing prejudice, self-stigma occurs (Link, 1987; Link & Phelan, 2001). Therefore, as people become aware of a stigma they may begin to agree with it. After agreement with the stigma they may then internalize its stereotypes and corresponding prejudices. This then can have a negative impact on self-esteem and self-efficacy, leading to shame. These last two aspects (low self-efficacy and shame) contribute to the "why try" effect (Corrigan, 2011) which diminishes a patient's belief that a treatment will alleviate their distress (Corrigan et al., 2013;

Mojtabai et al., 2011; SAMHSA, 2012). To understand the proposed mechanism of change with MHPN, stigma in mental health and its effects on treatment adherence will be explored.

Mental Health Stigma and its Effects on Treatment Adherence

The lasting effects of mental illness stigma are associated with a divide between experiencing emotional distress and seeking care (Corrigan et al., 2014). The end result of stigma, and where its impact is felt in regards to treatment seeking, is through its formation of person-level and provider/system level barriers to care (Corrigan, 1999; Link & Phelan, 2001), wherein each serve to undermine care seeking and service participation. (Corrigan et al., 2014) Person-level barriers include attitudes and behaviors that affect health decisions and are related to avoiding or dropping out of treatment prematurely. Person-level barriers also include having beliefs that treatment is ineffective or culturally irrelevant (Corrigan et al., 2014). Whereas provider and system-level barriers include staff cultural and psychological incompetence, as well as workforce limitations, such as low funding for behavioral health, which are influenced by stigma (Corrigan et al., 2014). As such, stigma impacts care seeking at personal, provider, and system levels.

To better understand how these barriers negatively affect treatment adherence and care seeking, theoretical models have been developed to elucidate psychological factors that hinder finding and acting on effective services (Kovandžić et al., 2011; Pescosolido, 1992). These models emphasize the integration of both social and cognitive theories in an ever-evolving way. These models demonstrate that in the face of distress, whether it is physical, emotional, or interpersonal, an individual may perceive it as a problem that may or may not require intervention depending on their level of distress (Pescosolido, 1992). A Transtheoretical or stages-of-change model is helpful for understanding this process (Prochaska & DiClemente,

1982). When a patient perceives distress, they are faced with decision of whether or not to engage in care. Oftentimes this decision involves a cost-benefit analysis of treatment options. During this analysis, stigmatizing labels will be perceived as a cost that can lead to worsened self-stigma and shame (Clement et al., 2015).

However, stigma does not only affect the initial decision to initiate treatment.

Unfortunately, many drop out soon after treatment commencement. In fact, research suggests that up to 26.2% of people may discontinue treatment prematurely (Fernandez, Salem, Swift, & Ramtahal, 2015). Stigma is a likely factor undermining poor treatment participation as negative perceptions of mental health, and prejudices associated with treatment, can often interfere with intervention adherence. Given this, it would be helpful for providers to check with patients to assess the reasons related to non-adherence, a necessary component of MHPN.

Mitigating the Effects of Stigma Through Mental Health Patient Navigation

Due to the negative associations of stigma with care seeking and treatment adherence, there has been a great deal of research into interventions with efficacy in reducing the negative impact of stigma. The relationship between stigma and care seeking may be moderated by three variables—knowledge, culture, and network—all of which can be directly addressed through MHPN. While MHPN, in general, can be viewed as a systems-level intervention through its education of staff and organizational normalization of mental health, it is provided individually to patients and, thus, it is through its reduction of self-stigma that the effects of MHPN may be most profound.

A body of research has emerged examining the impact of approaches to decreasing selfstigma and promoting personal empowerment (Mittal, Sullivan, Chekuri, Allee, & Corrigan, 2012). Approaches have been divided into three groups: (a) psychoeducation, (b) disclosure, and (c) support (Corrigan et al., 2014). Psychoeducation that involves reviewing facts about mental illness and addressing stigma is the most evaluated intervention and has been found to be effective in decreasing self-stigma (Corrigan et al., 2014). Psychoeducation is a component inherent to MHPN. Patient navigators engage patients in discussions that educate the patient on the high prevalence rates of mental illness and its association with cancer and its treatment. Navigators assist the patient in understanding the signs and symptoms of depression and make attempts to normalize their emotional experience.

While psychoeducation has shown efficacy in decreasing stigma, it is likely not sufficient as it is recommended that programs must also promote self-affirming attitudes such as recovery, empowerment, and self-determination (Corrigan, 2013). Another core component of MHPN is shared decision making, which is comprised of cost-benefit analysis, education, and support. By implementing these components, shared decision making promotes self-determination through an exchange between patient and health-care provider (Drake, Deegan, & Rapp, 2010; Joosten et al., 2008). Ample research supports using shared decision making for a variety of illnesses and disabilities including cancer (Gattellari, Butow, & Tattersall, 2001; Van Roosmalen et al., 2004) and mental illness (Ludman et al., 2003; Malm, Ivarsson, Allebeck, & Falloon, 2003; Von Korff et al., 2003). Of prime importance is the goal of assisting decision making by helping the patient examine costs and benefits of health options. Namely, the patient is encouraged to identify and evaluate advantages and disadvantages of a specific service for a specific problem (symptoms, disabilities, low quality of life) caused by the illness.

Another means of mitigating stigma is through communication utilizing user-friendly information channels (Tanis, 2008). The chief concern, in regards to the appropriate information

channel, is who is best suited to communicate the information and what qualities must this person integrate into this transmission. Health-decision making is primarily a "social discourse" between the patient and provider (Tanis, 2008). Therefore, there are certain qualities that enhance the exchange of information to positively affect treatment decisions. These include client-centered approaches (Tanis, 2008) such as active listening skills as well as person-centered notions of genuineness, empathy, and unconditional positive regard (Rogers, 1957) to assist the patient in identifying adaptive health decisions that they collaboratively agree on with the provider. Within MHPN the navigator enters into each encounter using a client centered approach as a means of normalizing and validating the patient's distress as the two parties collaborate in identifying a treatment option that the patient agrees he or she can engage in.

One last intervention that has efficacy in decreasing stigma (Corrigan, 2013) is the use of Motivational Interviewing (MI). MI can be viewed as a form of shared decision-making that addresses stages of change in treatment decision-making. It expands the cost-benefit analysis into a counseling process resting on four basic principles: (a) expressing empathy, (b) developing discrepancy, (c) rolling with resistance, and (d) supporting self-efficacy (Miller & Rollnick, 2003). Expressing empathy and use of reflective listening by the treatment provider establishes a non-judgmental atmosphere, helps individuals feel the provider is fully present, and leads to the development of a collaborative relationship. By developing discrepancy, the provider does not try to persuade the individual's views of how a particular behavior might help achieve or interfere with particular goals. Instead, it creates agency within the patient as they become motivated to engage in change behaviors such as engagement in treatment. This is a counseling style that patient navigators rely on when engaging patients in collaborative discussions regarding their mental health treatment decisions.

It is proposed that the components included in our MHPN intervention may reduce the self-stigma of individuals who engage in navigation. Specific MHPN components that may decrease the stigma of mental illness include validating and normalizing distress, providing individualized psychoeducation, discussing effective treatment modalities, engaging in collaborative treatment decision making, and using motivational interviewing to increase adherence to referrals. As such, MHPN may increase mental health treatment adherence within a cancer population through its mitigation of stigma perceived by the patient. Ultimately, this increase in mental health treatment adherence is likely to decrease rates of morbidity associated with depression in cancer populations.

SUMMARY

Current standards for screening, diagnosing, and treating depression in cancer patients are insufficient. As such, the status quo is failing to both identify and, consequently, provide care for potentially large numbers of at risk patients who may potentially meet criteria for depression. With recent findings of an increased prevalence of depression in patients in the acute stage of diagnosis (first two years post initial diagnosis) (Krebber et al., 2014), it is likely that a majority of these patients are falling through the screening and treatment gap inherent in the current paradigm. To fill this significant gap in the identification and treatment of patients, the UT Southwestern Moncrief Cancer Institute, an affiliate of UT Southwestern Harold C. Simmons Comprehensive Cancer Center, recently expanded its standard of care to include an integrated and collaborative approach to mental health screening, diagnosis, and treatment by providing measurement-based care for depression. The standard of care now implemented incorporates all of these components and is referred to as Mental Health Screening, Assessment, and Navigation (MH-SCAN). To our knowledge, no published reports have analyzed whole screening, diagnosis, and treatment programs (including longitudinal outcomes) within a heterogeneous cancer population (Thalén-Lindström et al., 2013). Therefore, the goals of this study are designed to fill this gap in the literature through the evaluation of its aims in a study sample diagnosed with cancer within two years of their initial depression screening.

Aims

- Describe the baseline clinical and demographic characteristics of patients who endorse
 clinically significant symptoms of depression versus those who do not endorse clinically
 significant symptoms of depression.
- Describe the baseline clinical and demographic characteristics of patients who endorse
 mild or greater depressive symptoms and are navigated versus those who are unable to be
 navigated.
- 3. Determine if depression treatment adherence is greater in those patients who are able to be navigated versus those who are unable to be navigated.
- 4. Determine if patients who are able to be navigated show more significant decreases in depressive symptom severity versus those who are unable to be navigated.

Hypotheses

- 1. Patients who screen positive for depression are hypothesized to be younger, more recently diagnosed with cancer, have lower socioeconomic status, not be married, and have a pre-existing mental illness versus patients who screen negative for depression.
- 2. Patients who are navigated are hypothesized to be of lower SES, more likely to have been diagnosed with malignant and aggressive forms of cancer, have less social support, endorse more severe depressive symptoms, and be older as compared to patients who are unable to be navigated.
- 3. Patients who are navigated are hypothesized to have greater depression treatment engagement versus patients who are unable to be navigated.
- 4. Patients who are navigated are hypothesized to achieve greater depressive symptom reduction versus patients who are unable to be navigated.

CHAPTER THREE Methods

The UT Southwestern Institutional Review Board has reviewed the referenced project and determined that it does not meet the definition of human subject research at 45 CFR 46.102.

SITE DESCRIPTION

The UT Southwestern Moncrief Cancer Institute (UTSW MCI) is a community based cancer prevention, treatment, and support center serving the social, emotional, and physical needs of individuals with cancer and their support network. As a leader in the community's efforts to fight cancer and reduce its burden throughout the continuum of care, UTSW MCI provides leading-edge services in cancer care to the uninsured, underinsured, and medically underserved within Tarrant and the surrounding counties in North Texas. These efforts include direct outpatient oncology treatment, education and community awareness, prevention and early detection, patient navigation, cancer survivorship planning, behavioral science support, and the implementation of innovative technologies to advance research.

PATIENT POPULATION

Patients who present to UTSW MCI for services come from a variety of referral sources, including oncology and general providers within the immediate and surrounding counties, as well as the local private hospitals, safety net hospitals, and UTSW in Dallas. UTSW MCI also engages in significant community outreach and advertising efforts, particularly for services that target traditionally underserved populations (e.g., for preventive mammography) within Tarrant County and surrounding rural counties, as patients can self-refer for services as well. In addition, patients can present at the UTSW MCI Mobile Survivorship unit that provides services to multiple rural counties, as well as to the Mobile Mammography unit that covers another large

number of local and rural counties. In sum, patients who receive services at UTSW MCI are not from a specific referral stream; they reflect a typical community population who present due to physician referral, word-of-mouth, and general advertising efforts.

MH-SCAN Implementation

Prior to beginning the study, this writer was involved in the development, planning, and implementation of the Mental Health Screening, Assessment, and Navigation (MH-SCAN) program which was launched as part of the standard of care at UTSW MCI as of September 2015, for all patients that are 12 years age or older. Although patients may present for services at UTSW MCI for a variety of treatment-related reasons, patients targeted for inclusion in the MH-SCAN program were from specific programs within UTSW MCI and are as follows: (1) Community Survivorship Program, (2) Genetics, (3) Early Detection, and (4) Psychology.

Survivorship Program

The UTSW MCI Survivorship program consists of a support program designed to address the ongoing needs of cancer survivors (an individual is considered a cancer survivor from the time of diagnosis, through the end of his or her life) as they continue in and/or after completion of active treatment. This is a no-cost program available to all cancer survivors in the community. At program enrollment, all participants meet at least once with a registered nurse and then a social worker for an initial assessment, information, and referrals to services within UTSW MCI, such as a referral to psychology, dietician, oncology exercise specialist, and/or genetic counselors, as well as other specialists within the community. A Physician's Assistant is also available to provide primary care services for survivors who otherwise do not have access to ongoing primary care or require a bridge to additional care.

Genetics

The clinical cancer genetics program is comprised of 11 board-certified genetic counselors and over 20 clinical sites throughout Dallas and Fort Worth via telegenetics, including within the safety-net hospital systems. The program provides hereditary cancer risk assessment for patients with any oncologic indication, with several funding sources to assist with covering the cost of genetic testing for many who are unable to pay.

Early Detection

Early Detection services at UTSW MCI currently consist of preventive and repeat mammography services, clinical breast exams, and cervical cancer screenings by trained oncology nurses and mammography technicians, as well as traditional nurse navigation services for those with questionable results. Early Detection services at UTSW MCI specifically conduct outreach to traditionally underserved populations within the local and surrounding counties.

Psychology

Clinical psychologists and pre-doctoral psychology interns treat patients from a variety of sources as well, including direct referrals from within UTSW MCI and from providers in the community. Patients can also directly self-refer for mental health assessment and treatment, with the only requirement being that they are affected by cancer in some way.

There are other programs within UTSW MCI in which patients receive services who were excluded from the MH-SCAN program for various reasons. Patients treated at the Simmons Cancer Center (SCC) at UTSW MCI were excluded due to SCC having their own distress

UTSW MCI (urology, organ transplant) were excluded as these clinics were functioning at UTSW MCI due to a treatment space agreement, not a specific cancer treatment program or protocol. Patients presenting at UTSW MCI Mobile Mammography for routine mammograms were also excluded at this time, due to staffing limitations. Well-insured patients utilizing imaging services were excluded because they did not have a provider visit other than with an imaging technician from UTSW. Lastly, patients utilizing telegenetics were excluded as these patients do not have access to the necessary screening technology at their home clinics, as were genetics patients receiving services per "Surgical Decision" or "New diagnosis of BRCA" due to the patient being informed within the past 24-48 hours of a diagnosis of cancer and/or severe genetic complication which would likely result in high rates of false positives on the screening measures. Lastly, patients presenting solely for a genetics-related blood draw were not included, as they do not have a provider visit that day with a genetics counselor or other provider.

Study Inclusion Criteria

Patients included in data analysis for this study are 18 or older and have been diagnosed with cancer within the last two years (i.e., "recent" cancer diagnosis). The study focuses on patients with recent diagnoses because depression is more prevalent in the acute (initial diagnosis and treatment) phase of the disease (Krebber et al., 2014).

MEASURES

Vital Sign⁶

All measures used for MH-SCAN were administered in the clinic, on hand-held tablets through VitalSign⁶ (VS⁶). The Center for Depression Research and Clinical Care at UT Southwestern developed VitalSign⁶ as a comprehensive program, incorporating elements of health information technology. VS⁶ is a point-of-care web-based application used to screen for depression and monitor symptoms using standardized clinical assessments. These assessments are then used to inform treatment planning and medical decision-making using measurement based care (MBC). The primary measure used to identify patients that are positive for experiencing emotional distress is the Patient Health Questionnaire (PHQ-2). Patients that screen positive on the PHQ-2 (≥3) are then prompted to complete the remainder of the PHQ-9 and the following questionnaires: (1) Patient Adherence Questionnaire (PAQ) (Warden et al., 2014), (2) Frequency, Intensity, and Burden of Side Effects Rating (FIBSER) (Wisniewski, 2006), (3) Generalized Anxiety Disorder 7 (GAD-7) (Spitzer, 2006), (4) Pain Frequency, Intensity, and Burden Scale (P-FIBS)(dela Cruz et al., 2014), (5) Concise Associated Symptoms Tracking – Self Report Scale (CAST-SR) (Trivedi, Wisniewski, Morris, Fava, Kurian, et al., 2011), (6) Concise Health Risk Tracking Scale (CHRT) (Trivedi, Wisniewski, Morris, Fava, Gollan, et al., 2011), and the (7) Alcohol and Drug Use screen (for description of all component measures of VS⁶ see Appendix A). Furthermore, patients who screened positive were contacted via phone for follow-up, approximately two weeks later, for re-screening and engagement with the Mini International Neuropsychiatric Interview (MINI) to assist in diagnostic clarification if no clinical or diagnostic interview had been completed by another trained provider.

Outcome Measures

Depression Symptom Severity

The Patient Health Questionnaire 2 (PHQ-2) is a two item self-report measure used for depression screening. The two questions assess the two core symptoms of major depression: (1) depressed mood and (2) loss of interest or pleasure in things usually enjoyed. The Patient Health Questionnaire 9 (PHQ-9) is a nine-item, self-report inventory that assesses symptoms in all nine domains of a major depressive episode and is validated as a reliable depression screening tool and measure of depression severity (Kroenke, Spitzer, Williams, & Löwe, 2010). The utility of the PHQ-9 has been demonstrated in both primary care (Arroll et al., 2010; Kroencke, Spitzer, & Williams, 2001b) and oncology outpatients (Ell et al., 2008; Fann et al., 2008; Randall et al., 2013; Thekkumpurath et al., 2011; Wagner et al., 2017) as it has been found to be a highly sensitive (89 to 96%) brief screening tool (Kroencke, Spitzer, & Williams, 2001a; Whooley, Avins, Miranda, & Browner, 1998). For each item the individual indicates how much they have been "bothered" by the symptom over the past two weeks. Responses are rated on a 4 point Likert-type scale (not at all = 0, several Days = 1, more than half the days = 2, nearly every day = 3). Scores ranging from 5-9 signify mild symptom severity, 10-14 correspond to moderate symptom severity, 15-19 indicate symptoms of moderate to severe severity, and scores >20 indicate severe symptomology. Initial PHQ-9 scores serve as the baseline symptom severity measure, while the last PHQ-9 score, within one year of baseline, is used as the outcome measure for depression severity. This study will use the PHQ-9 depression measure as the initial screening measure to identify all patients with depression. After initial screening via the PHQ-9, patients found to experience depressive symptoms will be assessed for other co-morbid psychiatric symptoms.

Navigation Status

Navigation status represents patients' engagement in the navigation program. First, patients were classified by whether they agreed to navigation, denied navigation, failed to return navigation follow-up calls, had incorrect contact information, or were removed from navigation call lists due to death or entering into the final stages of hospice care. For purposes of statistical analysis, the variable was collapsed into two groups: (1) able to be navigated and (2) unable to be navigated. Patients that were able to be navigated were able to be contacted and agreed, upon initial follow up, to participate in navigation services. Patients were classified as being unable to be navigated if they failed to return follow-up navigation calls, had incorrect contact information in the EHR, denied navigation services, or were deceased or entered into hospice care.

Treatment Engagement

Treatment engagement was defined as either engaging in referred depression treatment or non-engagement with referred depression treatment. Patients that engaged in treatment were determined to have done so either by documentation of a treatment encounter in the EHR or, if seeking treatment at an outside facility, through documentation of treatment engagement in navigation encounters. Due to some patients being placed on a waitlist for psychotherapy at UTSW MCI or delayed time in obtaining a scheduled appointment in the community, patients were considered to have engaged in treatment if they did so while receiving Mental Health Patient Navigation services.

Symptom Remission

Symptom remission is reached when scores on the last PHQ-9 are below the clinical threshold for depression (<5). Symptom remission was coded as a dichotomous variable (Yes or No).

Number of Screens

A proxy variable for length of time in treatment was calculated. The proxy variable used was number of PHQ-9 screens. This variable was used to control for length of time in treatment/and or navigation.

Predictive and Descriptive Measures

All predictive and descriptive variables were obtained via chart review or calculated based on data obtained via chart review. Data was collected either through patient encounter notes with UTSW MCI staff, in scanned program enrollment forms, or pathology/laboratory results. When discrepancies between provider notes and patient report were observed regarding SES or demographic information, data from the latter was prioritized due to concern of staff error in documentation. If discrepancies were observed between self-report and pathology/laboratory reports in regards to clinical information, data from pathology/lab reports were prioritized for analysis.

Demographic Data

Demographic data included gender, race, ethnicity, and age at screening. Furthermore, due its descriptive nature of the study sample, days since initial cancer diagnosis was included as

a demographic characteristic. The number of days since initial cancer diagnosis was calculated by subtracting the date of initial screen from date of diagnosis and is a continuous variable.

Gender. The variable of gender was dichotomous and categorical. Patients were grouped as either being Male or Female.

Ethnicity. The variable of ethnicity was categorical in this study and was grouped by Hispanic or Latinx, Non-Hispanic or Latinx, or Other. For purposes of statistical analysis the group of "other" was collapsed with Non-Hispanic or Latnix.

Race. The variable of Race was categorical and patients were grouped as Black or African American, White Hispanic, White Non-Hispanic, or Other.

Socioeconomic Data

Variables collected as socioeconomic indicators include Marital Status, Education,
Employment, Reported Household Income, and the patients' calculated Percentage of the
Federal Poverty Level. Another indicator, Estimated Household Income, was calculated using
the patient's zip code identified during chart review.

Marital Status. Marital Status was collected as a categorical variable. The variable of Marital Status was initially divided into Married, Divorced, Widowed, Separated, and Never Married. However, for purposes of statistical analysis, the categories of Divorced, Widowed, or Separated were collapsed into "Formerly Married."

Education. The variable of Education was collected as a categorical variable and was initially grouped by No High-school Degree, High-school Degree, Some College (Associates or Trade), College Degree, and Advanced Degree. However, for purposes of statistical analysis patients that reported having No High-school Degree, High-school Degree, and Some College were collapsed into "No College or Advanced Degree."

Employment Status. Employment status represents patient's employment at time of initial screening. Employment status contained four groups: Employed (Part or Full time), Unemployed, Retired, and On Disability.

Reported Household Income. Reported household income was collected as a categorical variable. Patients were initially grouped as reporting earning less than \$10,000; \$10,000 to \$29,999; \$30,000 to \$49,999; and \$50,000 or more. However, for purposes of statistical analysis when comparing patients who were and were not able to be navigated those earning \$30,000 to \$49,999 and \$50,000 or more were collapsed due to a lack of data needed for appropriate statistical analyses.

Estimated Household Income. The Estimated Household Income variable was created by matching the patient's reported postal Zip Code to that zip code's median annual household income from 2015 Census Data (Census Bureau, 2015). Estimated Household Income was divided into three groups: less than \$30,000; \$30,000 to \$49,999; and \$50,000 or more.

Percentage of Federal Poverty Level. The Percentage of Federal Poverty level (FPL) was obtained by dividing total annual household income by the poverty guideline for household size (Health and Human Services, 2017). As part of the survivorship program at UTSW MCI, the patient typically meets with a Licensed Social Worker (LCSW) during the initial encounter who calculates the FPL to identify possible health insurance subsidies for which they may be eligible. The FPL for each patient was only used for data analysis if it was calculated by the social worker at that time. The variable was comprised of four groups: < 100% FPL, 100% to 150% FPL, 150% to 200% FPL, and > 200% FPL. Lower percentages of FPL indicate being further below the established Federal Poverty Level, per 2015 and 2016 guidelines as applicable.

Patient Medical History

Variables included as part of patients' Medical History include Pre-Existing Mental Illness (Yes or No), Moncrief Cancer Institute Survivorship program enrollment (Yes or No), Genetic Carrier status (Yes or No), and Family History of Cancer (Yes or No); all were dichotomous categorical variables.

Patient Oncology Characteristics

Active Cancer Treatment. Active in cancer treatment was coded as a dichotomous variable (Yes or No). Cancer treatment was defined as being active if the patient was in curative treatment at time of baseline screening. Patients that were in palliative care were categorized as not being in active treatment. Data was collected through the EHR in each patient's treatment plan.

Cancer Treatment Type. Patients were initially categorized as being in Chemotherapy, Radiation, Surgery, Hormone, Immunotherapy, Other Therapy, and No Current Treatment. However, for purposes of statistical analysis the variable was collapsed into chemotherapy, other, or no current treatment. Cancer treatment type was a categorical variable.

Cancer Staging. Cancer staging was grouped as being in Stage 0, I, II, III, or IV. Cancer staging was obtained through examination of pathology/laboratory results or treatment summaries. Cancer staging was a categorical variable.

Metastasis. Whether or not a patient was diagnosed with metastatic cancer was determined through examination of pathology/laboratory results or through cancer treatment summaries. Metastasis was a dichotomous categorical variable (Yes or No).

Cancer Site. Cancer sites were grouped by SEER cancer categories. Cancer site was a categorical variable and includes the following sites: Breast, Hematological and Bone/Soft

Tissue, Digestive System, Female Genital System, Lung, Male Genital System, Head and Neck, Urinary System, Endocrine, and Skin.

Diagnosed Psychopathology

The Mini International Neuropsychiatric Interview (MINI) is a brief, semi-structured, diagnostic interview for 17 Axis I diagnoses according to DSM-IV and ICD-10 (International Statistical Classification of Disease) criteria (Sheehan et al., 1998). The MINI has been shown to have high validity in relation to the Structured Clinical Interview for DSM-5 and the Composite International Diagnostic Interview for ICD-10 (Sheehan et al., 1997; Tolin et al., 2016). The MINI was used to inform diagnostic formulation within the MH-SCAN program and is administered following a second positive score (≥5) on the PHQ-9 during follow-up.

PROCEDURE

Initial Screening and Re-assessment Process

All patients included in the MH-SCAN program completed initial screening and, later, reassessment via the VS⁶ program adhering to the process detailed in the Initial Screening Workflow, which is illustrated in detail in Figure 1. Each day every MH-SCAN eligible patient that was scheduled for an appointment at UTSW, was flagged in the electronic health record (EHR), indicating that the patient was due for screening or re-assessment through the VS⁶ program. When the patient checked in for the appointment, the front desk staff provided the patient a handheld tablet computer, provided verbal encouragement to complete the screener as part of general patient care, and assisted with troubleshooting any technology related issues. If results were positive (≥5 on the PHQ-9) these results were sent via e-mail to both the provider

seeing the patient and the Mental Health Patient Navigator. If the patient endorsed suicidal ideation, the scheduled member of the Suicide Risk Assessment Team was alerted (See Figure 2 for Crisis Team Management Workflow) and appropriate steps were taken for assessing and insuring safety. Providers discussed positive results with their patients, and briefly gathered relevant treatment history and information regarding their current distress. Patients were then informed that a Mental Health Patient Navigator would be contacting them within one to two weeks to follow-up. If the patient was seeing a provider who has specific mental health treatment training (e.g., Physician Assistant, Psychologist, or Psychology Intern), the patient may be evaluated via diagnostic interview and either receive or be referred to appropriate treatment during that visit.

Mental Health Patient Navigation

For all patients who screened positive on the PHQ-9, a trained Mental Health Patient Navigator (Clinical Psychology Doctoral Student Intern or Clinical Psychologist) followed up with the patient within one to two weeks of initial positive screen to re-assess symptom severity, determine psychiatric diagnoses, assess any current psychosocial treatment, give appropriate treatment referrals, and navigate the patient to appropriate resources either within UTSW MCI or the patient's existing treatment environment (e.g., primary care, treating psychiatrist, psychologist).

Upon first contact, the Patient Navigator re-assessed depressive symptom severity through the VS^6 program. Patients who continued to endorse mild depressive symptoms (≥ 5 on the PHQ-9) were engaged in the MINI to assist in diagnostic formulation if no prior diagnosis existed. VS^6 was designed to guide providers with treatment planning and medical decision-making using measurement-based care. Thus, within the VS^6 program, the Patient Navigator

selected from measurement based care options including external specialty care interventions, all of which served as the basis for referral recommendations. Measurement based care options included psychiatric treatment, psychotherapy, and other therapy (i.e., exercise classes, support groups, other therapy). The Patient Navigator assisted the patient in obtaining access to treatment sources and was then responsible for following up with the patient roughly every two weeks to re-assess symptom severity and treatment adherence, until symptom remission.

Follow-up then continued every three months the first year post-remission of depressive symptomology, and every six months for the second year (see Figure 3 for detailed Mental Health Patient Navigation Workflow). The patient was asked if they would like to continue or terminate participation in the MH-SCAN program at each contact.

Referral Process

The Patient Navigator used a collaborative and shared-decision making process when referring patients for treatment as this has been shown to increase treatment adherence (Storm & Edwards, 2013). The Patient Navigator used PHQ-9 treatment recommendations based on PHQ-9 score to inform the referral process (Kroenke, Spitzer, et al., 2010). Recommendations are as follows: patients with mild symptoms (scores of 5-9) are recommended to receive support, engage in psychoeducation, and continue to be monitored; patients with moderate symptoms (scores of 10-14) are recommended to receive the same suggested interventions for mild symptoms plus discussion of antidepressant or psychotherapy should be discussed; those with moderately severe symptoms (scores of 15-19) are recommended to be referred for antidepressant or psychotherapy; and those with severe symptoms (scores of 20+) are recommended to be referred for antidepressant and psychotherapy. However, through the collaborative process, if the Patient Navigator and patient believed another intervention or type

of therapy (e.g., financial advising with social work, support group, exercise) would better address the patient's distress, those intervention options were also included as possible referrals. Furthermore, if during follow-up, it was observed that the patient demonstrated no significant gains in treatment the navigator collaboratively identified ways to potentially augment treatment for the patient.

DATA ANALYSIS

Data Screening and Preparation

The VitalSign⁶ (VS⁶)data management team extracted VS⁶ data for all patients with initial screening results on the PHQ-2 between 10/1/2015 and 10/1/2016. From this dataset, 500 patients with cancer diagnoses within two years of initial screen were selected for inclusion in the study. Data for analysis included subsequent VS⁶ reassessment data for the following year post baseline. A research team member performed chart reviews to add clinical and demographic data to the dataset of 500 patients. The medical record number was removed and the deidentified dataset was used for statistical analysis. No identifying information linking it to the original VS⁶ database was maintained. The de-identified dataset was used for statistical analyses. All data analyses were performed using SPSS software version 23 (SPSS. Inc. Chicago, IL).

Analytical Plan for Hypothesis Testing

more recently diagnosed with cancer, have lower socioeconomic status, not be married, and have a pre-existing mental illness versus patients who screen negative for depression. For hypothesis 1 the primary outcome variable is depression-screening result (Positive vs. Negative) based on initial PHQ-9 score. Descriptive statistics were used to summarize the demographic, socioeconomic, and clinical variables. To evaluate Hypothesis 1 patients were divided into two groups based on screening result and were then analyzed for statistically significant differences between demographic, socioeconomic, and clinical variables, using chisquare for categorical and t tests for continuous variables. Effect sizes were calculated for t tests, (Cohen's d) and for chi-squares (Cramer's V) (Cohen, 1988). Cohen's d values signify the

Hypothesis 1: Patients who screen positive for depression are hypothesized to be younger,

following effect size: 0.2 is a small effect, 0.5 is a medium effect, and 0.8 is a large effect.

Cramer's *V* values signify the following effect size: 0.1 is a small effect, 0.3 is a medium effect, and 0.5 is a large effect.

Exploratory Analysis. Due to the recent identification of increased sensitivity and specificity of the PHQ-9 with a depression cut off score that is greater or equal to 10 (Wagner et al., 2017), groups were created to compare patient characteristics based on the original cut of score of ≥ 5 as well as the higher cut off score of ≥ 10 . As such, three groups were created from initial PHQ-9 scores. Patients were grouped into the following three groups based on initial screening score: "<5," "5 to 9," and " ≥ 10 ." The three groups were then analyzed for statistically significant differences between demographic, socioeconomic, and clinical variables, using chi-square for categorical and t tests for continuous variables.

Hypothesis 2: Patients that were navigated are hypothesized to be of lower SES, more likely to have been diagnosed with malignant and aggressive forms of cancer, have less social support, endorse more severe depressive symptoms, and be older versus patients who were unable to be navigated.

For Hypothesis 2 the primary outcome variable was navigation status. This variable was used to compare those that were navigated versus those that were unable to be navigated. Statistically significant differences between groups were identified through Chi-square analyses for categorical and *t* tests for continuous variables.

Hypothesis III: Patients who are navigated are hypothesized to be more likely to engage depression treatment versus patients who are unable to be navigated.

For Hypothesis 3, the primary outcome variable was engagement in treatment for depression. To evaluate Hypothesis 3, patients were divided into two comparison groups based on navigation

status. A Chi-square analysis was utilized to identify if there were statistically significant differences in depression treatment engagement.

Hypothesis 4: Patients who are navigated are hypothesized to achieve greater depressive symptom reduction versus patients who are unable to be navigated.

The primary outcome variable for Hypothesis 4 is the difference between the first and last PHQ-9 score within one year of initial screen. Patients were again grouped on navigation status for evaluation of Hypothesis 4. To determine if there was a significant reduction in depressive symptom severity, a one-way analysis of variance (ANOVA) was performed with the difference between last and first PHQ-9 score as the dependent variable and navigation status as the independent variable. The effect size for this analysis (η^2 , Eta Squared) was calculated (Cohen 1988). Eta squared values signify the following effect sizes: 0.01 is small, 0.056 is medium, 0.138 is large.

A secondary outcome variable, symptom remission, was also used to evaluate Hypothesis

4. A chi-square analysis was conducted on navigation status and symptom remission to
determine if there was a statistically significant difference in patients reaching remission in
symptoms of depression.

To evaluate the potential impact that navigation had on symptom reduction a six stage hierarchical regression was performed with the difference between last and first PHQ-9 score as the dependent variable while navigation status, treatment engagement, and number of PHQ-9 screens were independent variables. Characteristics that differentiated patients who were and were not able to be navigated were entered in as stage one through three to control for their effects. Navigation status was entered as stage four, treatment engagement as stage five, and number of PHQ-9 screens as stage six. Navigation status was entered at stage one and treatment

engagement in stage two. Variables were entered in this order, as it seemed plausible given that patients engaged in treatment due to the intervention of navigation.

Exploratory Analysis. Two sets of exploratory analyses were conducted to further determine the impact navigation status had on depression symptom reduction. The first exploratory analyses was conducted due to differential attrition resulting in more than 50% of patients in the unable to navigate group missing a "last screen." Therefore a sensitivity analysis was conducted assess the impact of missing data. Missing data was accounted for in the following six different ways: (1) last observation carried forward (LOCF) (this assumes patients had no change in symptom severity between first and last screen); (2) Imputed missing data using the mean value from all patients who were observed to have a reduction in symptoms (this assumes patients with missing data saw the same reduction in symptoms as the mean for the entire sample); (3) Imputed missing data using the mean value by group who were observed to have reduction in symptoms (This assumes that patients with missing data saw the same reduction in symptoms as others in the group); (4) Imputed missing data using the mean value from all patients who were observed to have an increase in symptom severity (This assumes that patients with missing data saw the same mean increase in symptom severity for the sample); (5) Imputed missing data using the mean value from unable to navigate patients who were observed to have an increase in symptom severity (This assumes that patients with missing data saw the same mean increase in symptoms symptom severity as others in the group); and (6) Excluding patients with missing data. A one-way analysis of variance (ANOVA) was then run using each method of missing data management. See Appendix B for results of the sensitivity analysis.

CHAPTER FOUR

PATIENT POPULATION AND DIFFERENTIAL ATTRITION

The study sample was derived from 3,598 patients initially screened with the PHQ-2 via VitalSign⁶ (VS⁶) as part of the MH-SCAN program at UT Southwestern Moncrief Cancer Institute (UTSW MCI) between 10/1/2015 and 10/1/2016 (see Figure 4 for Differential Attrition Flow Chart). Five hundred patients with recent cancer diagnoses were selected for inclusion in the study. Patients were ordered based on ascending medical record number. Chart review was conducted to determine date of cancer diagnosis. Patients were included in the study sample if the date of cancer diagnosis was within two years of initial depression screen. This process continued until 500 patients were determined to meet criteria for study inclusion. This group of 500 will henceforth be referred to as the study sample.

The mean baseline PHQ-9 score for the study sample was 5.54 (SD = 7.33), with scores ranging from 0 to 27 (50^{th} percentile = 2.00, 75^{th} percentile = 11.00, 90^{th} percentile = 18.00, 95^{th} percentile = 20.95). Within the study sample, the majority (n = 327, 65.4%) screened negative (< 5) on the PHQ-9. The mean PHQ-9 score for patients who screened negative was 0.80 (SD = 0.92). The remaining 34.6% (n = 173) patients screened positive with a mean PHQ-9 score of 14.49 (SD = 5.54).

Attempts were made to contact all 173 patients who screened positive in order to enroll in navigation. However, 67 (38.7%) were unable to be navigated due to either not returning calls (n = 55), declining navigation services (n = 8), or inability to contact due to incorrect contact information in the electronic health record (n = 4). The remaining 106 (61.27%) were contacted and agreed to participate in navigation services. The mean PHQ-9 score for patients that agreed

to navigation was 14.21 (SD = 5.66) while the mean for those that were unable to be navigated was 14.94 (SD = 5.37). An independent t-test was run to determine if there were differences in mean PHQ-9 scores between patients who agreed to navigation and those that were unable to be navigated. There were no outliers in the data, as assessed by inspection of a boxplot. PHQ-9 scores for both levels of navigation status were normally distributed, as assessed by Shapiro-Wilk's test (p > .05), and there was homogeneity of variances, as assessed by Levene's test for equality of variances (p = .937). Independent t-tests reflected no statistically significant differences in baseline PHQ-9 mean scores for patients that agreed to navigation and those who were unable to be navigated, t (179) = -.069, p = .946, 95% CI (-1.92 to 1.79).

BASELINE CHARACTERISTICS

Demographic Baseline Characteristics

On average, patients included in the study sample were diagnosed with cancer, on average, within 10 months (M = 293.84 days, SD = 229.99 days) of their initial PHQ-9 assessment. The study sample was middle-aged (M = 53.71, SD = 12.14), and the majority (n = 380, 76%) were female. See Table 1 for all demographic characteristics. The total sample was comprised of 28.6% Hispanic or Latinx and 68.8% Non-Hispanic patients. Of the patients who identified as Non-Hispanic, 24.4% of the total sample self-identified as Black or African American and 41.4% of the total sample identified as White Non-Hispanic.

Socioeconomic Baseline Characteristics

See Table 2 for frequencies and percentages of all socioeconomic characteristics. In examining marital status, 240 (48.0%) patients were married, 122 (24.4%) were formerly married, and 106 (21.2%) were never married. Within the characteristic of education, 233 (46.6%) patients lacked a college or advanced degree whereas 105 (21.0%) had obtained such a degree. However, 162 (32.4%) patients' data on education was missing in the EHR.

One hundred and forty five (29.0%) patients were employed, while 121 (24.2%) were unemployed, 60 (12.0%) were retired, and 99 (19.8%) were on disability. Reported household income for the sample reflected that 52 (10.4%) patients reported earning less than \$10,000; 80 (16.0%) reported earning \$10,000 to \$29,999; 16 (3.2%) reported earning between \$30,000-\$49,999; and another 16 (3.2%) reported earning greater than \$50,000 annually. A large percentage (67.2%) of reported household income data was missing. The estimated household income for the sample reflected 109 (21.8%) patients earning under \$30,000; 140 (28.0%) patients earning between \$30,000-\$49,999; and 251 (50.2%) patients' household estimated income was greater than \$50,000. For percentage of federal poverty level (FPL), 170 (34.0%) patients earned less than 100% FPL, 85 (17.0%) earned between 100% and 150% FPL, 74 (14.8%) earned 150% to 200% FPL, and 86 (17.2%) earned greater than 200% FPL. Percentage of federal poverty level was missing from 85 (17%) patients' EHR.

Medical History Baseline Characteristics

See Table 3 for full report of patient medical history. Most patients (n= 318, 63.6%) did not have a pre-existing mental illness. The majority (n=447, 89.0%) were enrolled in the survivorship program at UTSW MCI. The majority of data about genetic carrier status was

missing (n= 359, 71.8%) but 24.0% of patients tested negative for genetic mutations while 4.2% were positive. Most patients (n=300, 60.0%) had a family history of cancer, with 12.2% of family cancer history data missing.

Oncology Baseline Characteristics

See Table 4 for full report of patient oncology characteristics. The majority (n=174, 60.8%) of patients were not active in cancer treatment at the time of baseline screen. Of those active in cancer treatment (34.8%), 128 (25.6%) were being treated with Chemotherapy and 46 (9.2%) were engaged in another form of treatment. Other forms of treatment included dual Chemotherapy and Radiation (2.8%), Radiation alone (2.4%), Hormone Therapy (1.2%), Immunotherapy (0.2%), and Surgery (0.8%). See Figure 5 for chart of cancer treatment. Patient cancer staging was distributed with 14 (2.8%) patients diagnosed at Stage 0, 74 (14.8%) at Stage I, 75 (15.0%) at Stage II, 98 (19.6%) at Stage III, 84 (16.8%) at Stage IV (See Figure 6 for chart of cancer staging). However, 155 (31%) patients' data on cancer staging was missing from the EHR. Metastatic cancer was found to occur in 88 (17.6%) of the study sample, with 26.6% of data on metastatic status missing. Two hundred and five (41.0%) patients were diagnosed with Breast Cancer. Other common cancer sites were Hematological, Bone, and Soft Tissue (n=56, 11.2%); Digestive System (n=55, 11%); Female Genital System (n=53, 10.6%); and Lung (n=36, 7.2%). Remaining cancer types included Male Genital (n=28, 5.6%); Head and Neck (n=21, 4.2%); Urinary System (n=16, 3.2%); Endocrine (n=11, 2.2%); and Skin cancer (n=9, 4.2%)1.8%). See Table 4 and Figure 7. .

HYPOTHESIS 1: COMPARING POSITIVE VS. NEGATIVE INITIAL SCREENS

For Aim 1 it was hypothesized that patients who screen positive for depression on their baseline PHQ-9 would be younger, more recently diagnosed with cancer, of lower socioeconomic status, not married, and have a pre-existing mental illness.

Demographic Comparisons

An independent-sample t-test was used to evaluate age and days since cancer diagnosis between depression screening groups (positive vs. negative). There were no outliers in the data, as assessed by inspection of boxplots. Age and days since initial cancer diagnosis for negative vs. positive screens were normally distributed (Shapiro-Wilk's test p > .05). There was homogeneity of variances, as assessed by Levene's test for equality of variances, for days since diagnosis but not for age at initial screening (p = 0.960, 0.037 respectively). Patients who screened positive for depression were significantly younger (M = 52.07, SD = 11.31) than those who screened negative (M = 54.58, SD = 12.48), t(498) = -2.21, p < .05, (See Table 1). There was no statistical difference (t = 1.40, t = 1.61) between groups when evaluating days since initial cancer diagnosis.

A chi-square test of independence was conducted on gender, ethnicity, and race between positive and negative screens. When comparing patients who screened positive vs. negative, there were no statistically significant differences in gender ($\chi^2 = 0.01$, p = .909) ethnicity ($\chi^2 = 0.93$, p = .336), or race ($\chi^2 = 5.81$, p = .121) (see Table 1).

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Socioeconomic Indicator Comparisons

See Table 2 for frequencies, percentages, and comparisons of all socioeconomic variables. A chi-square test of independence was run on each socioeconomic indicator. When comparing patients who screened positive vs. negative on marital status, a statistically significant difference was identified, $\chi^2(2) = 15.832$, p < .05, V = .15. There were significantly more patients who were married and screened negative (Adjusted Standardized Residual = -3.2), while there were significantly more patients who were formerly married that screened positive (Adjusted Standardized Residual = 2.0). For those that screened positive 2.3% of marital status data was missing while 8.6% of data for patients who screened negative was missing.

When comparing patients who screened positive vs. negative on education status a statistically significant difference was identified, $\chi^2(2) = 10.65$, p < .05, V = .17. There were significantly more patients who lacked a college or advanced degree that screened positive (Adjusted Standardized Residual = 3.1) while there were significantly more patients that screened negative who had attained such a degree (Adjusted Standardized Residual = -3.1). For patients that screened positive 17.9% of education status data was missing while 40.1% of data for patients that screened negative was missing.

When comparing patients who screened positive vs. negative on employment status a statistically significant difference was identified $\chi^2(3) = 12.604$, p < .05, V = .17. There were significantly more patients who were on disability and screened positive (Adjusted Standardized Residual = 3.4). For patients that screened positive 8.7% of employment status data was missing while 18.3% of data for patients that screened negative was missing.

When comparing patients who screened positive vs. negative on reported household income a statistically significantly difference was identified, $\chi^2(3) = 8.118$, p < .05, V = .22.

There were significantly more patients that reported earning 30,000 to \$49,999 who screened positive (Adjusted Standardized Residual = 2.6). For patients that screened positive 46.2% of reported household income data was missing while 78.3% of data for patients that screened negative was missing.

There were no significant differences on estimated household income ($\chi^2 = 1.99$, p = .370) or patient's federal poverty level percentage ($\chi^2 = 1.47$, p = .689). See Table 2 for standardized adjusted residuals indicating directionality of differences.

Patient Medical History Comparisons

See Table 3 for all frequencies, percentages, and comparisons on all medical history characteristics. When comparing patients who screened positive vs. negative on pre-existing mental illness a statistically significant difference was identified, $\chi^2(1) = 144.596$, p < .001, V = .54. There were significantly more patients with a pre-existing mental illness who screened positive (Adjusted Standardized Residual = 12). When comparing patients who screened positive vs. negative on enrollment in the survivorship program a statistically significant difference was identified, $\chi^2(1) = 8.133$, p < .01, V = .13. There were significantly more patients who were enrolled in the survivorship program that screened positive (Adjusted Standardized Residual = 2.9).

No statistically significant difference was identified between genetic carrier status (χ^2 =0.02, p = .880) and screening positive vs. negative for depression. However, it should be noted that genetic carrier data was missing for 74.0% and 70.6% for patients that screened positive and negative respectively. No significant difference was identified for family history of cancer (χ^2 = 0.01, p = .913) and screening positive vs. negative for depression.

Patient Oncology Characteristic Comparisons

See Table 4 for all frequencies, percentages, and comparisons on all oncology characteristics. A chi-square analysis was run on each oncology characteristic. No statistically significant associations were found for active cancer treatment ($\chi^2 = 1.36$, p = .244), cancer treatment type ($\chi^2 = 3.42$, p = .181), cancer staging ($\chi^2 = 2.99$, p = .558), metastasis ($\chi^2 = 0.19$, p = .664), or cancer site ($\chi^2 = 9.61$, p = .383). However, it should be noted 28.9% of cancer staging data for patients that screened positive and 32.1% for patients that screened negative was missing. Twenty six percent of metastatic data was missing for patients that screened positive and 26.9% of metastatic data was missing for patients that screened negative.

HYPHOTHESIS 2: NAVIGATION STATUS COMPARISONS

For Aim 2 it was hypothesized that patients who are navigated would be of lower SES, more recently diagnosed with malignant and aggressive forms of cancer, have less social support, endorse more severe depressive symptoms, and be older when compared to patients who were unable to be navigated.

Demographic Comparisons

See Table 5 for frequencies, percentages, and comparison statistics. An independent-sample t-test was used to evaluate age and days since cancer diagnosis in comparing patients that were navigated and those that were unable to be navigated. All assumptions were tested and met. Independent t-tests reflected no statistically significant differences in age (t = 2.13, p = .147) or days since cancer diagnosis (t = 2.16, t = .143) at baseline. Chi-square analyses were applied to

all categorical variables. All expected cell counts were greater than five. Analyses revealed no significant associations between gender ($\chi^2 = 2.29$, p = .131), ethnicity ($\chi^2 = 0.99$, p = .318), or race ($\chi^2 = 3.32$, p = .146).

Socioeconomic Comparisons

See Table 6 for frequencies, percentages, and comparison statistics. Chi-square analyses were run on each socioeconomic variable. When comparing patients who were able to be navigated vs. unable to be navigated on reported household income a statistically significant difference was identified, $\chi^2(2) = 13.99$, p < .001, V = .39. There were significantly fewer patients that reported earning less than \$10,000 per year who were able to be navigated (Adjusted Standardized Residual = -3.7). Reported household income data was missing for 34.0% of patients who were navigated and 65.7% of patients who were unable to be navigated.

No statistically significant differences were identified for marital status ($\chi^2 = 3.81$, p = .149) education ($\chi^2 = 0.95$, p = .329), employment status ($\chi^2 = 0.61$, p = .894), estimated household income ($\chi^2 = 2.48$, p = .289), or percentage of federal poverty level ($\chi^2 = 2.36$, p = .501). However, data on FPL was missing for patients who were able to be navigated (21.4%) and unable to be navigated (19.4%).

Patient Medical History Comparisons

See Table 7 for frequencies, percentages, and comparison statistics. Chi-square analyses were applied to each variable. When comparing patients who were able to be navigated vs. unable to be navigated no statistically significant differences were identified for having a pre-existing mental illness ($\chi^2 = 0.02$, p = .900), being enrolled in the UTSW MCI survivorship program ($\chi^2 = 0.13$, p = .718), being a genetic carrier ($\chi^2 = 0.65$, p = .420), or having a family

history of cancer ($\chi^2 = 0.52$, p = .473). However, missing data accounted for 68.9% of genetic carrier data for patients that were able to be navigated and 82.1% of patients who were unable to be navigated. Family history of cancer data was missing for 8.5% of patients that were able to be navigated and 20.9% of patients that were unable to be navigated.

Patient Oncology Characteristic Comparisons

See Table 8 for frequencies, percentages, and comparison statistics. Chi-square analyses were applied to all variables. When comparing patients who were able to be navigated vs. unable to be navigated on metastasis a statistically significant difference was identified, $\chi^2(1) = 4.515$, p < .05, V = .19. Significantly more patients who did not have metastatic cancer were able to be navigated (Adjusted Standardized Residual = 2.1). Data on metastasis was missing for 21.7% of patients who were able to be navigated and 32.8% of patients who were unable to be navigated.

When comparing patients who were able to be navigated vs. unable to be navigated on cancer staging a statistically significant difference was identified, $\chi^2(8) = 12.32$, p < .05, V = 0.19. There were significantly more patients with stage I cancer who were able to be navigated (Adjusted Standardized Residual = 2.9). Significantly fewer patients with stage IV cancer were able to be navigated (Adjusted Standardized Residual = -2.0). Data on cancer staging was missing for 23.6% of patients who were able to be navigated and 37.3% of patients who were unable to be navigated. No statistically significant differences were identified for being active in cancer treatment ($\chi^2 = 0.23$, p = .632), current cancer treatment type ($\chi^2 = 0.55$, p = .758) or cancer site ($\chi^2 = 13.56$, p = .147).

MENTAL HEALTH PATIENT NAVIGATION

Essential components of mental health patient navigation are the MINI Diagnostic interview and supplying appropriate referrals. Of the 106 patients that were navigated, 27 (25.5%) endorsed symptoms that met criteria for Major Depressive Disorder, 21(19.8%) endorsed symptoms that met criteria for an Adjustment Disorder, and 21 (19.8%) endorsed symptoms that met criteria for co-morbid Depression and Anxiety. Twenty four (22.6%) patients did not meet criteria for a psychiatric diagnosis (See Table 9 for frequencies and percentages of all Psychiatric Diagnoses). Of the 106 patients that were navigated, n=80 (75.5%) were referred to treatment. The majority (n= 54, 50.9%) of navigated patients were referred to psychotherapy, while 16 (15.1%) were referred to adjunctive medication management in coordination with psychotherapy. A minority of patients were referred either to medication management alone 4.7%, adjunctive psychotherapy (3.8%), or other (0.9%) which included various group support programs or exercise programs. See Table 10 for frequencies and percentages of navigation referrals.

Forty one (23.7%) patients who endorsed clinically significant symptoms of depression reported experiencing suicidal ideation. Twenty four (13.9%) reported having thoughts of death several days, n=10 (13.9%) reported having thoughts of death more than half the days, and n=7 reported having thoughts of death nearly every day during the two weeks prior to PHQ-9 Screening (Question 9 on the PHQ-9).

Hypothesis 3: Engagement in Treatment for Mental Illness

For Aim 3 it was hypothesized that patients who were able to be navigated would have statistically greater depression treatment engagement when compared to patients who were unable to be navigated.

Seventy one (67.0%) navigated patients initiated referred treatment while 6.0% of patients who were not navigated initiated treatment. Thirty five (33.0%) navigated patients were non-adherent with referred treatment whereas 63 (94.0%) patients who were not navigated were non-adherent with referred treatment. To evaluate Hypothesis 3 a chi-square test of independence was conducted between engagement in treatment and navigation status. and a statistically significant difference was identified, $\chi^2(1) = 62.224$, p < .001, V = .60. Significantly more patients who were able to be navigated engaged in referred treatment (Adjusted Standardized Residual = 7.9)(See Table 11).

Hypothesis 4: Symptom Reduction

For Aim 4 it was hypothesized that patients who were navigated would demonstrate a more significant reduction in symptom severity than those that were not able to be navigated.

Results from the sensitivity analysis (see Appendix B) indicate the most valid method to account for missing PHQ-9 data is to use the last observation carried forward.

To evaluate Hypothesis 3 a one-way ANOVA was conducted to determine if symptom reduction was different for patients that were navigated compared to those that were unable to be navigated. There were no outliers, as assessed by boxplot; data was normally distributed for each group, as assessed by Shapiro-Wilk test (p > .05); and there was homogeneity of variances, as assessed by Levene's test of homogeneity of variances (p > .05). Symptom reduction, as assessed

with the PHQ-9, was statistically different between patients that were navigated (M = -6.43, SD=6.63) than those that were unable to be navigated (M = -1.46, SD=3.87), F(1, 171) = 30.91, p < .001, $\eta^2 = .15$ (See Table 13 and Figure 8).

Forty (37.74%) patients that were navigated reached symptom remission, and only 6 (8.96%) patients who were unable to be navigated reached symptom remission. To further evaluate hypothesis 4 chi-square analysis was performed to determine if there were significant differences in navigation status on symptom remission. A statistically significant difference was identified, $\chi^2(1) = 17.42$, p < .01, V = .32. There were significantly more patients who were navigated and reached symptom remission (Adjusted Standardized Residual = 4.2).

Relationship Between Navigation and Symptom Reduction

Given the significant difference in reduction of depressive symptoms between patients that were navigated compared to those unable to be navigated, a hierarchical multiple regression was completed to determine how much of the variance in symptom reduction could be explained by navigation.

Prior to conducting a hierarchical multiple regression, the relevant assumptions of this statistical analysis were tested. There was linearity as assessed by partial regression plots and a plot of standardized residuals against the predicted values. There was independence of residuals, as assessed by Durbin-Watson statistic of 2.346. There was homoscedasticity, as assessed by visual inspection of a plot of standardized versus unstandardized predicted values. There was no evidence of multicollinearity, as assessed by tolerance values greater than 0.1 (See Table 14 for Correlation Matrix). There were not standardized deleted residuals greater than ±3 standard deviations, no leverage values greater than 0.2, and values for Cook's distance above 1. The assumption of normality was met, as assessed by Q-Q Plot.

A six stage hierarchical multiple regression was conducted with mean symptom remission as the dependent variable (see Table 15). Reported household income, metastasis, and cancer staging were entered into stage one, two, and three, respectively, to control for their impact on symptom remission as these variables were significantly different in patients who were navigated compared to patients not able to be navigated. Navigation status was entered at stage four, treatment engagement at stage five, and number of PHQ-9 administrations at stage six. These independent variables were entered in this order, based on the assumption that navigated patients would engage in treatment, which, in turn, corresponds to an increase in number of screens.

The hierarchical multiple regression revealed that reported household income, metastasis, and cancer staging does not contribute significantly to explaining the variance in PHQ-9 symptom reduction (F= 0.19, p > .05; F = 0.75, p > .05; F = 1.51, p > .05 for Models 1, 2, 3 respectively). Adding navigation status into the model (Model 4) explained an additional 22.0% of the variance in symptom reduction and this change in R^2 was significant, F (1,168) = 18.84, p < .001, Adding treatment engagement to the regression model (Model 5) explained an additional 6.2% of the variance in symptom reduction and this change in R^2 was significant, F (1, 167) = 5.71, p < .05. However, the contribution of navigation status was no longer significant while cancer stage and treatment engagement did significantly contribute. The addition of number of screens into the regression model (Model 6) did not significantly explain the variance in depression symptom reduction, ΔF (1,166) = 0.04, p > .05, even though the model was significant, F (6,171) = 5.30, p < .01. Therefore, Model 5 was the best model, accounting for 35.0% of the variance in symptom reduction. The most important predictor of symptom

reduction in Model 5 was treatment engagement, which explained 6.2% of the variation in symptom reduction, and cancer stage.

EXPLORATORY ANALYSIS

PHQ-9 Score Group Comparisons

Due to recently published research that the PHQ-9 has higher specificity and sensitivity in oncology patients with scores at ≥ 10 indicating a positive screening result (Wagner et al., 2017), groups were created to compare patient characteristics based on the original cut of score of ≥ 5 as well as the higher cut off score of ≥ 10 . Therefore three groups were created: Group 1 (initial PHQ-9 < 5), Group 2 (initial PHQ-9 = 5 to 9), and Group 3 (initial PHQ-9 ≥ 10).

Descriptive statistics (see Table 16) are as follows: Group 1 was comprised of 327 patients, Group 2 of 39, and Group 3 of 134. Mean initial PHQ-9 scores were 0.80 (SD = 0.92), 6.79 (SD = 1.54), and 16.73 (SD = 4.08) for Groups 1, 2, and 3, respectively.

Patient Demographic Comparisons by PHQ-9 Group

Patient demographic characteristics for these 3 groups are presented in Table 16. Chisquare analyses were performed on each categorical variable. There were no significant differences when comparing the three groups on gender ($\chi^2 = 0.93$, p = .629), ethnicity ($\chi^2 = 3.47$, p = .176), or race ($\chi^2 = 10.53$, p = .104)

One-way ANOVAs were performed on age at initial screen and days since initial cancer diagnosis. No statistically significant difference was identified for days since cancer diagnosis (F = 1.01, p = .366). However, there were differences between groups for age at initial screen. There were no outliers, as assessed by boxplot; data was normally distributed for each group, as assessed by Shapiro-Wilk test (p > .05); and there was homogeneity of variances, as assessed by

Levene's test of homogeneity of variances (p = .155). Age at initial screening was significantly different among the PHQ-9 Groups, F(2, 497) = 3.84, p < .05, $\eta^2 = .02$ (Table 20).

Mean age for Group 1 was 54.58 (SD = 12.48), Group 2 was M = 54.90 (SD = 9.82), and Group 3 was 51.25 (SD = 11.62). Tukey post hoc analysis reflected mean age for Group 1 was significantly older than Group 3 (3.34, 95% CI [.43, 6.25], p < .05) (Table 21).

Patient Socioeconomic Indicator Comparisons by PHQ-9 Group

Chi-square analyses were conducted on each SES indicator (See Table 17). When comparing groups on marital status a significant difference was identified, $\chi^2(4) = 15.832$, p < .01, V = .13 (See Table 17 for adjusted standardized residuals indicating direction of association). When comparing groups on education status a significant difference was identified, $\chi^2(2) = 10.646$, p < .01, V = .18. When comparing groups on employment status a significant difference was identified, $\chi^2(6) = 14.859$, p = .021, V = .13. No statistically significant differences were identified for reported household income ($\chi^2 = 6.53$, p = .163), estimated household income ($\chi^2 = 3.15$, p = .532), and federal poverty level percentage ($\chi^2 = 4.84$, p = .564).

Patient Medical History Characteristics by PHQ-9 group

When comparing groups on pre-existing mental illness a statistically significant difference was identified, $\chi 2(2) = 146.599$, p < .001, V = .54. (Table 18). See Table 18 for adjusted standardized residuals indicating direction of association. There were no statistically significant differences between being a genetic carrier ($\chi^2 = 0.71$, p = .706) or having a family cancer history ($\chi^2 = 0.12$, p = .941). When comparing groups on enrollment in the UTSW MCI survivorship program a statistically significant difference was identified, $\chi^2(2) = 9.49$, p < .01, V = .14.

Patient Cancer Characteristic Comparisons by PHQ-9 groups

There were no statistically significant differences identified when comparing PHQ-9 group on being active in cancer treatment (χ^2 = 1.55, p = .461), cancer treatment type (χ^2 = 4.41, p = .354), having metastatic cancer (χ^2 = 1.14, p = .567), cancer staging (χ^2 = 6.65, p = .575) or cancer site (χ^2 = 21.81, p = .241) (See Table 19).

CHAPTER FIVE Discussion

This study sought to gain clarity into (1) patient characteristics that differentiate cancer patients who experience clinically significant depressive symptoms from those patients who do not experience significant symptoms and (2) to determine if the Mental Health Screening, Assessment and Navigation (MH-SCAN) program, with its use of Mental Health Patient Navigation (MHPN), has evidence supporting its utility in successfully filling the screening and treatment gap inherent in the current status quo. The study achieved these goals, as the results contribute four important points to the field of psychosocial oncology. First, evidence was found supporting the efficacy of the PHQ-9 as a screening tool and the ability of MH-SCAN to identify patients experiencing depressive symptoms. Second, it successfully revealed important findings on patient characteristics associated with increased distress and risk for depression. Third, this study begins to shed light on characteristics of patients who are likely to engage in and benefit from navigation services. Fourth, MH-SCAN can be implemented in a community cancer center and achieve its desired effects of accurately identifying patients experiencing symptoms of depression, refer them to appropriate treatment, and achieve symptom remission, thereby successfully filling the screening and treatment gap. In the following sections these key findings will be discussed in detail.

PHQ-9 and Depression Prevalence

Approximately 34% of patients in the study sample who had been diagnosed with cancer within the past two years, screened positive for depression (PHQ-9 score > 4). Of those, 22.5% had a PHQ-9 score of 5 to 9 and 77.5% with a score of 10 or greater. This is consistent with previous studies that have identified higher rates of depressive symptoms among patients within the acute phase of diagnosis (i.e., two years post diagnosis) (Krebber et al., 2014), and replicates findings of oncology patients that screen positive for depression on the PHQ-9 being more likely to be in higher score thresholds (Wagner et al., 2017).

Question 9 of the PHQ-9 assesses suicidal ideation. It should be noted that within the study sample approximately 8% endorsed having thoughts of death. This provides further evidence of the efficacy in using the PHQ-9 in an oncology populations as this replicates previous findings of 6-11% of cancer patients having suicidal thoughts (Leung et al., 2013; Rao et al., 2012; Spencer et al., 2012).

Following initial positive screening, all patients within MH-SCAN who are contacted and agree to mental health patient navigation (MHPN) are engaged in either a clinical or diagnostic interview using the MINI Diagnostic Interview. Of the 106 patients who were navigated, one quarter endorsed symptoms that met criteria for Major Depressive Disorder. This finding is similar to another study analyzing prevalence rates of depression in acute phase oncology populations (Krebber et al., 2014), therefore lending further credence to PHQ-9 as a suitable screening tool in oncology settings.

Patient Characteristics Associated with Depression

Hypothesis 1 was largely confirmed. There were significantly more patients who were younger, of lower socioeconomic status, unmarried, and have a pre-existing mental illness that screened positive for depression on their initial PHQ-9. However, oncology characteristics hypothesized to also differentiate patients that screened positive and negative for depression were not supported.

Support for Hypothesis 1 comes from the identification that specific demographic, socioeconomic, and medical history characteristics did statistically differentiate those that were and were not experiencing clinically significant symptoms of depression. These characteristics can be potential risk factors vigilant clinicians could utilize as warning signs for those that are more likely to experience depression.

For example, while no differences in gender, race or ethnicity were found to differentiate patients in the study sample in terms of their propensity to screen positive for depression, one demographic characteristic did. As hypothesized, it was found that age was associated with an increased likelihood of endorsing clinically significant depressive symptoms. The study revealed that younger patients were significantly more likely screen positive on a measure of depressive symptoms. The mean age, although technically younger among those who screened positive, was only approximately two years different from those that screened negative. As such, clinically significance of this finding is lacking.

Further backing for confirmation of Hypothesis 1 comes from results that support previous findings, which identified decreased social support and lower socioeconomic status as risk factors for the development of depression (Chochinov et al., 1997; Kadan-Lottick et al., 2005; Lloyd-Williams et al., 2003). Cancer survivors who were married were significantly less

likely to screen positive on the PHQ-9 than those that were not currently married (i.e., formerly married or never married). Marriage may be a protective factor for patients against depressive symptoms when experiencing the stress of their cancer diagnosis and treatment, as spousal support has been shown to be associated with increased problem-focused coping (Kang & Suh, 2015). Married survivors are able to rely on spousal support to assist in the numerous stressors associated with being diagnosed and engaging in treatment. Not only does a spouse offer assistance with transportation to and from appointments and the opportunity for increased household income, a spouse can also offer emotional support and assist in coping with stress (Applebaum et al., 2014).

Traditional SES indicators such as education, employment, and reported household income also differentiated patients in the study sample who did and did not endorse clinically significant symptoms of depression. Cancer survivors who lacked a college or advanced degree were significantly more likely to screen positive for depression. This may be due to those who do not have a degree lacking resources, which may bolster practical problem solving or emotional coping. In fact, prior research has revealed a relationship between education level and locus of control (Paula Braveman & Laura Gottlieb, 2014; Ibrahim, Kelly, & Glazebrook, 2013), with those with lower education having an external locus of control and maladaptive coping style. Therefore, it may be proposed that those who lack a college or advanced degree perceive the threat of cancer in a different way than those that do have such a degree and have more difficulty in coping with the stress.

Employment was another SES indicator that differentiated those that endorsed clinically significant symptoms of depression on the PHQ-9. In particular, cancer survivors on disability were significantly more likely to endorse symptoms of depression than those that classified

themselves as employed, retired or even simply unemployed. While it is possible that this is related to the strictly financial component of employment, there remains another possible conclusion. A risk factor for experiencing depression in cancer patients is decreased physical functioning (Gray et al., 2014). Therefore, this finding is likely due to patients who are on disability having more significant reductions in their physical functioning. However, due to the nature of this study it could not be determined whether the patient is on disability due to their cancer diagnosis or another chronic physical or mental illness.

The last SES indicator that differentiated those that screened positive and negative for depression was reported household income. Cancer survivors who reported earned between \$30,000 and \$40,000 per year were significantly more likely to screen positive on the PHQ-9 than those that reported earning less than \$30,000 or even more than \$50,000 per year. This may be due to patients who earn within this range being qualified as "the working poor" (Brady, Fullerton, & Cross, 2010). The working poor are at risk for numerous negative physical and psychosocial consequences (Braveman & L. Gottlieb, 2014). They often fail to qualify for low-income health subsidies and/or free healthcare offered to those that earn less than the federal poverty level, yet still do not earn enough to securely navigate the significant costs inherent in seeking cancer treatment. As such, there is added stress on this population that may increase their risk for developing depression (Rojas-García et al., 2015). However, approximately 70% of data was missing for this indicator. Therefore, results should be interpreted cautiously.

As has been previously documented (Chochinov et al., 1997; Lloyd-Williams et al., 2003), significantly more patients with a pre-existing mental illness screened positive for depression. It was observed that close to 70% of patients with a pre-existing psychiatric diagnosis endorsed symptoms of depression, whereas approximately 30% of those with a pre-

existing psychiatric diagnosis denied experiencing clinically significant symptoms of depression. Receiving a cancer diagnosis is a significant stressor and psychopathology has been known to occur when stressors exceed the inherent ability of an individual to cope (Farmer & McGuffin, 2003). Therefore, it is possible that those with a pre-existing mental illness may inherently have fewer resources to assist in coping, and that these limited resources become increasingly taxed in the face of this stressor.

Results from this study are striking in that surface-level difficulties such as undergoing current cancer treatment or having a metastatic disease were not associated with screening positive on the PHQ-9. Furthermore, other oncology characteristics that would be presumed to be associated with depression, such as more aggressive and debilitating forms of cancer, were also not associated with endorsing symptoms of depression. While varying rates of depression were seen by cancer site, in particular the finding of 37.6% of breast cancer patients screening positive, there remained no significant differences among those that screened positive and negative by type of cancer.

In summary, results indicate that individuals who have a pre-existing mental illness, are unmarried, have less education, are on disability, and earn between \$30,000 and \$40,000 per year (i.e., the "working poor") are more at risk for endorsing depressive symptoms than those who have no pre-existing mental illness, are married, have a college degree, not on disability, and either earn less than \$30,000 (i.e., likely to qualify for healthcare subsidies) or, alternatively, potentially earn enough to afford costly cancer treatment. These characteristics should signal clinicians for further evaluation of depression and may serve as a basis for more direct and refined distress screening programs.

Evaluations of Mental Health Patient Navigation

The MHPN program engaged in navigation 106 of the 173 patients who screened positive on the initial PHQ-9. This demonstrates a desire of patients to engage in a navigation program to assist in obtaining mental health care, and re-affirms previous studies that indicate a large percentage of oncology patients voice their desire for access to care (Kadan-Lottick et al., 2005).

Of the 67 patients who were unable to be navigated, 55 were the result of a failure to return generic messages left by patient navigators and 4 were unable to be contacted due to incorrect contact numbers or deceased status. Eight patients frankly declined participation in MHPN. While it cannot be presumed that a similar percentage of patients who were unable to be reached by phone would then agree to participation in the program, patients who could not be contacted offer an opportunity for improvement upon the navigation workflow.

Navigation Status Comparisons

Results failed to provide evidence in support of Hypothesis 2. Patients who were navigated and patients who were unable to be navigated were compared on demographic, socioeconomic status, medical history, and oncology characteristics. These two groups were observed to be very similar in regards to these characteristics. Previous research in which ethnic minorities and individuals with socioeconomically disadvantaged backgrounds are less likely to engage in specialty mental health care (Santiago, Kaltman, & Miranda, 2013) (Alegria et al., 2002), but evidence identified suggest no difference in engagement. Perhaps this suggests that an oncology population is unique in regards to utilization of mental health services. However, a more plausible explanation is that when mental health care is tailored to take into account the practical limitations associated with lower SES and/or addresses mental health stigma, ethnic

minorities and individuals from lower SES status can have equivalent mental health engagement (Goodman, Pugach, Skolnik, & Smith, 2013).

Despite the overarching demographic similarities between those that were navigated and unable to be navigated a few characteristics were found to differentiate the two groups. Of particular importance, it was determined that household income, cancer staging, and the occurrence of metastatic disease were significantly associated with navigation status. Cancer patients in this study whose reported household income was less than \$10,000 were significantly less likely than those that reported earning more than \$10,000 per year to be navigated. This association may be attributed to increased mental health stigma for those of lower SES (Gary, 2005); (Hatzenbuehler, Phelan, & Link, 2013). However, this difference may also be due to specific difficulty in contacting individuals reporting income less than \$10,000, as 82% of the unable to be navigated cases were due to not returning initial navigation phone calls.

While patients who were navigated and unable to be navigated were not different in terms of demographic or medical history characteristics, two oncology characteristics were associated with navigation status in a paradoxical manner, therefore failing to provide support for hypothesis 2. Patients who had lower staged and non-metastatic cancer were more likely to be navigated. This may be due to previous research revealing that patients with advanced-stage cancer have more frequent visits with their oncology team, and other supportive or palliative care personnel who may be more apt to attend to the patient's daily emotional needs (Jr & Richardson, 2012). Whereas patients with earlier staged cancer lack such contact leading to a sense of abandonment and isolation as they attempt to cope with the fear of recurrence (Fardell et al., 2016). Furthermore, within the current status quo of psychiatric treatment in an oncology population, the burden of treatment has primarily fallen to oncology providers, albeit with

significant gaps in care (Fisch, 2004; Kadan-Lottick et al., 2005); (Fallowfield et al., 2001; Greenberg, 2002; Meredith et al., 1996; Passik, Dugan, McDonald, Rosenfeld, Theobald, & Edgerton, 1998; Valente et al., 1993). Therefore it is also possible that a significant number of these patients with advanced-stage cancer are already receiving, or perceive they are receiving care for their depression by their treating oncologist.

Navigation and psychiatric treatment engagement

A crucial component of MHPN is the collaboration between patient and navigator in identifying appropriate treatment referrals and having the patient then engage in the referred treatment. The majority of navigated patients were referred to a specific modality of depression treatment, with a minority opted to be followed by a patient navigator for simply ongoing monitoring of their symptoms. Of the patients referred to treatment, approximately 70% engaged in the treatment collaboratively agreed upon with the navigator. This is a statistically significant and clinically meaningful difference when compared to patients who were not navigated, in which only 6% of patients engaged in mental health treatment. This finding provides direct support for the confirmation of Hypothesis 3.

While it is difficult to ascertain whether patients who were unable to be navigated were ever referred to a specific treatment, the evidence does lend credence to the value and ultimate aim of MHPN. Patients who were unable to be navigated can be seen as engaging in what is the current status quo in healthcare. Within the current paradigm, the burden for referring cancer survivors to mental health treatment falls to nursing, social work, and oncology clinical staff (Lazenby et al., 2015) (Lazenby, McCorkle, & Fitch, 2014), resulting in significant gaps in the utilization of psychiatric services (Hollingworth et al., 2013). As part of staff training prior to the implementation of the MH-SCAN program at UTSW MCI, all providers across programs (e.g.,

nurses, social workers, genetic counselors), were educated on the need and importance of reviewing results from the PHQ-9 screening and provide basic referrals for treatment. As such, the group who was unable to be navigated is in essence receiving services similar to what is seen in many NCI-designated cancer centers.

The MH-SCAN program identified 173 patients who were experiencing clinically significant symptoms of depression of which approximately one-quarter met criteria for major depressive disorder. One hundred and six (61.3%) of these 173 patients subsequently engaged navigation services which successfully assisted 67% in engaging in treatment. These findings are especially striking given previous research revealing that 74% of patients with a recent cancer diagnoses have unmet psychiatric needs (Zebrack et al., 2015). Therefore, it is possible that MH-SCAN can serve as a model for future screening and treatment programs and assist in filling this treatment gap.

Navigation and depressive symptom reduction

Results of the study provide support for the confirmation of Hypothesis 4. Patients who were navigated had a statistically significant greater reduction in symptoms of depression than those patients who were unable to be navigated. Engaging in the MHPN program resulted in patients who were able to be navigated experiencing a symptom severity reduction from moderate to mild in range. Furthermore, approximately 40% reached remission of depressive symptoms. These findings contrast with results revealing that patients who were unable to be navigated, while having similar baseline scores in the moderate range, continued to endorse symptoms of moderate severity at final screen, with less than 10% reaching symptom remission. Furthermore, it was determined that the impact of MHPN on symptom reduction was via an increased likelihood of navigated patients to engage in depression treatment. While it is possible

that the increase in likelihood of treatment engagement was due to overcoming stigma and breaking down barriers to care, this observational study did not collect data to evaluate this possible explanation. Despite this limitation, these findings provide increased support to the benefits of including MHPN alongside mental health screening programs for oncology clinics.

Due to the observational nature of this study, comparisons between groups of patients who were navigated and unable to be navigated may be confounded. Differential attrition resulted in over 50% of patients who were unable to be navigated missing a follow-up PHQ-9 screen. Furthermore, without strict control over screening time points there is a lack of consistency within pre and post measures. Therefore, it is possible to glean evidence as to the significance of MHPN by comparisons to more strictly controlled studies analyzing the impact of measurement-based care. Results from the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial revealed that first level measurement based care (MBC) treatment for acute depression treatment resulted in a 30.6% remission rate (A. John Rush et al., 2006), a rate that is comparable to the 38% seen through the implementation of MH-SCAN and its use of MHPN.

These findings provide strong evidence that Mental Health Patient Navigation has a significant effect on symptom reduction. Results suggest that the primary mechanism of this effect is through the ability of MHPN to significantly improve the likelihood of patients to engage in psychiatric treatment. As such, MH-SCAN and its use of MHPN was successful and confirmed the hypotheses that patients who are navigated will be more likely to engage in depression treatment and subsequently experience significant reduction in symptoms of depression.

STRENGTHS AND LIMITATIONS

This study was conducted as a non-randomized, observational study that evaluated the clinical outcomes of screening, assessment, and navigation; a program that was implemented clinic wide and is standard of care at UTSW-MCI. Conducting a study in a quasi-experimental design allowed for the observation of MH-SCAN in a community cancer clinic that is likely generalizable to other community cancer clinics in which 67% of oncology patients seek treatment nationwide (Community Oncology Alliance, 2014). Those seeking care at UTSW MCI are a valid representation of patients that are commonly seen in community cancer clinics that serve a heterogeneous population, both in terms of demographics, socioeconomic status, and oncology characteristics. This fact gives support to the idea that programs like MH-SCAN and its inclusion of MHPN are able to be implemented in other cancer clinics to better address the psychosocial needs of this at risk patient population.

However, the nature of an observational, quasi-experimental study offers several limitations as well. The primary limitations stem from differential attrition and missing data. Because this is an uncontrolled study, and is instead an observational evaluation of a standard of care program, data is sometimes limited and difficult to ascertain via chart review. This leads to certain patient characteristics having significant amounts of missing data due to omission from a patient's EHR. As such, inferences on differentiating patient characteristics must be made accordingly.

Furthermore, lack of control resulted in a majority of patients that were unable to be navigated lacking a post-intervention screen. Other confounds with comparing patients who were

navigated and unable to be navigated were discussed in depth previously but warrant further discussion. Because of its observational nature, patients were often screened at varying time points due to an inability of patient navigators to contact the patient for follow-up screens within the designed two-week period, or they missed treatment appointments at UTSW-MCI where they would otherwise be screened. However, although these limitations give rise to future research, it is perhaps worth noting that actual mental health treatment patient encounters and treatment patterns within the community are also far from the regimented protocols of randomized controlled trials.

There remains a dearth of literature examining the reduction of depressive symptoms following screening and referral to treatment in an oncology population. It is suggested that randomized controlled trials be conducted to further evaluate symptom reduction following screening and treatment programs, as well as more rigorously explore the effects that MHPN has on treatment engagement and symptom reduction. Studies should incorporate a control group for comparing these screening programs both with and without MHPN to better evaluate the specific impact of MH-SCAN and other programs.

Future research would benefit from the inclusion of other outcome measures. A measure of stigma would allow for the determination of whether stigma mediated the effects of MHPN, resulting in increased engagement in depression treatment. A measure of cancer treatment adherence would reveal whether psychosocial interventions have an effect on adherence to this care. Lastly, longitudinal data on physical health outcomes should be collected to determine whether or not the ultimate aim of MH-SCAN can be met, namely, reduced mortality in cancer patients diagnosed with comorbid depression.

Lastly, results identified critical data that can inform future iterations of the MH-SCAN program (See Figure 8 for proposed updated MHPN workflow). Anecdotally it was observed that patients who reported earning lower incomes had phone services canceled or suspended at various times during attempted navigation. This observation provides evidence of the need for patient navigators to make in-person attempts to engage in patient navigation (see Figure 8) and/or engage creative outreach solutions that take into account unstable income, phone numbers, or addresses (e.g., utilizing a free text message outreach service at the beginning of each month, when patients are more likely to have monthly subsidy income and access to prepaid phone minutes).

Other improvements involve automated exportation of VitalSign⁶ data; more rapid attempts to contact patients post initial positive screen, and gaining consent for release of information to the patient's oncology team. Automated exportation of VS⁶ data would reduce redundancy of documentation within the MH-SCAN program. This automation would also allow patient navigators to focus on contacting and navigating patients as opposed to spending time on reviewing and documenting VS⁶ results. Making attempts to contact patients more rapidly after initial positive screening may assist navigators making contact and may increase the likelihood of patients agreeing to participate in navigation services as they should have recently discussed these positive results with another provider at the clinic. In gaining consent for release of information to the patient's oncology team a more collaborative and holistic approach to treatment may be facilitated.

CONCLUSION

This study demonstrated that Mental Health Screening, Assessment, and Navigation can be implemented in a community cancer clinic and the desired goals of identifying patients experiencing depression, engaging them in treatment for their psychiatric illness, and reduce symptom severity can be achieved. Furthermore, the tablet based screening program, VitalSign⁶ and its use of the PHQ-9, was effective in identifying cancer patients that are experiencing depressive symptoms. Importantly, this study revealed that cancer patients who are within two years of cancer diagnosis and who are younger, of lower SES, lack social support, and have preexisting mental illness are most at risk for experiencing clinically significant symptoms of depression.

Mental Health Patient Navigation increased engagement in depression treatment with a corresponding significant reduction in depressive symptoms. It can be concluded that MHPN successfully bridges the gap that has been inherent in screening and treatment programs, and fulfills recent recommendations put forth by numerous psychoncology groups. MH-SCAN can serve as the model for future iterations of screening and treatment programs, providing crucial psychosocial care to at risk populations whose mental health has often gone underserved.

Figure 1

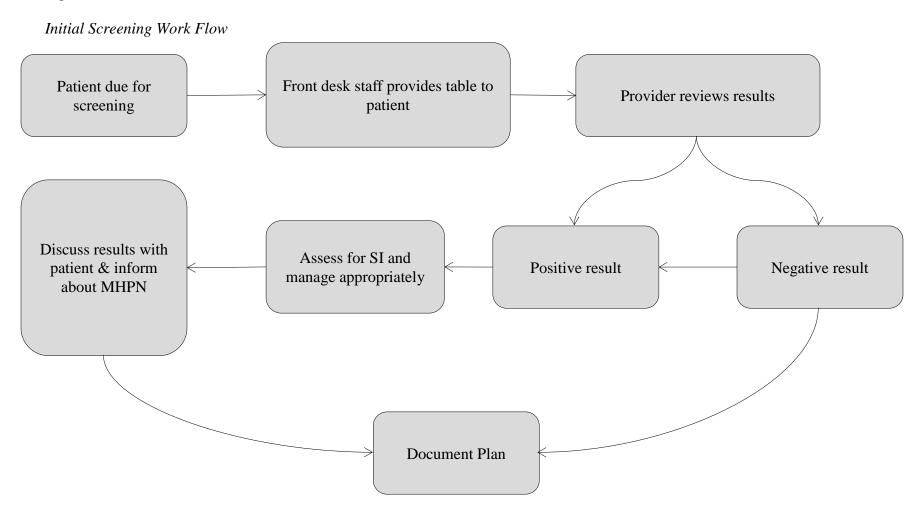


Figure 2
Suicide Risk Assessment Team Management Workflow.

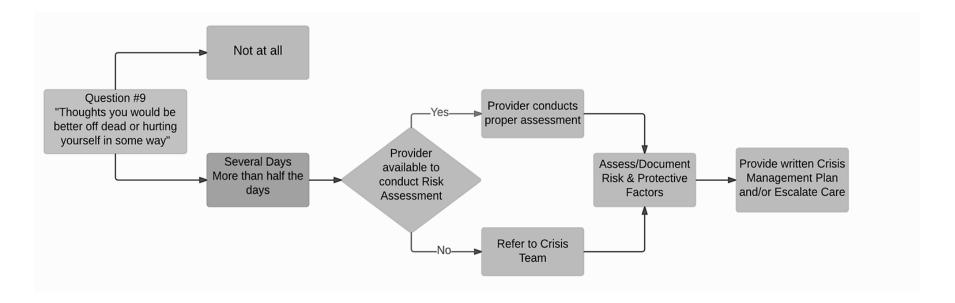


Figure 3

Mental Health Patient Navigation Workflow.

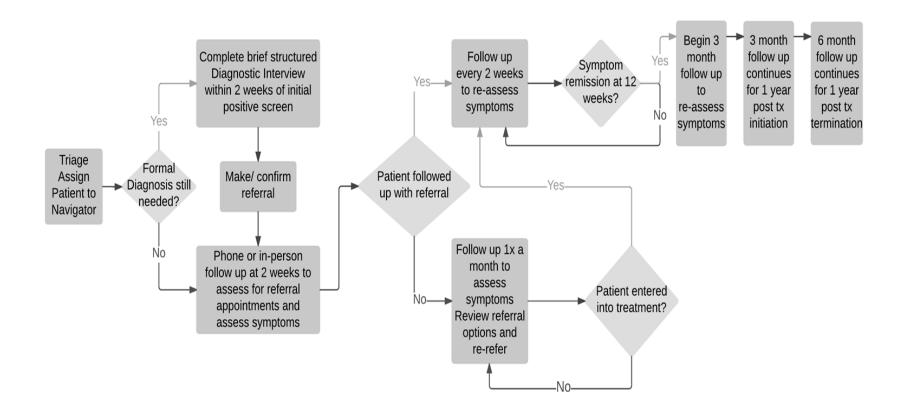


Figure 4

Patient Differential Attrition Study Flow

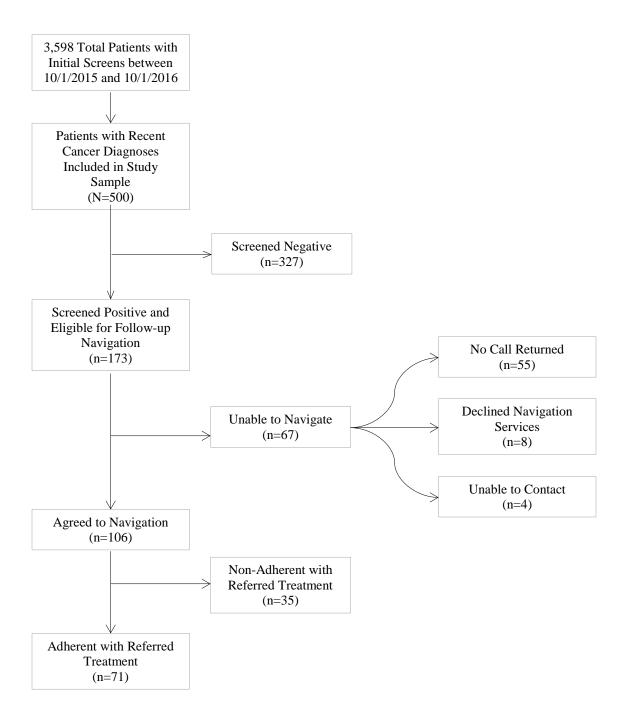


Figure 5

Cancer Treatment Type for All Patients (N=500)

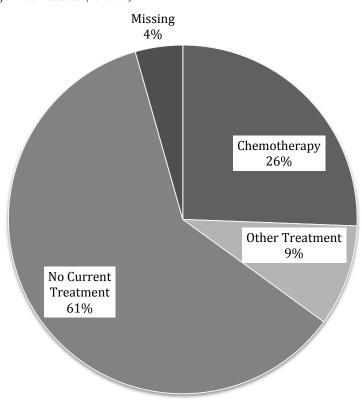


Figure 6

Cancer Stage at Screening for All Patients (N=500)

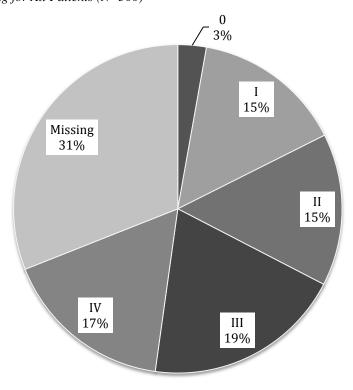
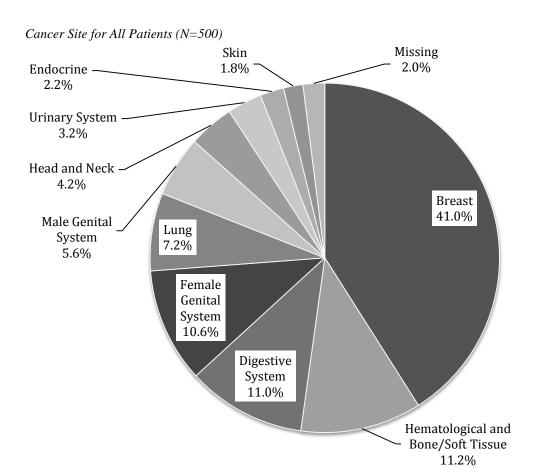


Figure 7



Mean Symptom Reduction from Initial Screen to Last Screen, by Navigation Status

Figure 8

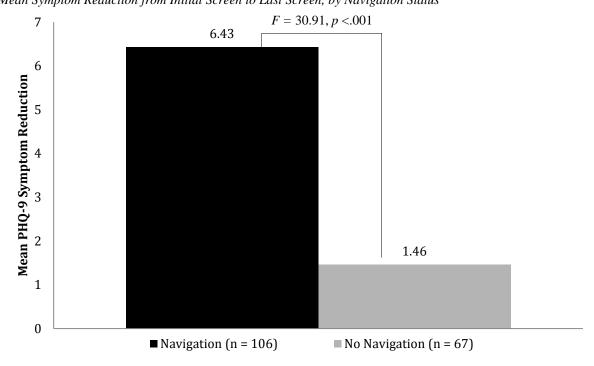


Figure 9

Post-Hoc Analysis: Bar Graph of Participants by PHQ-9 Cut Off Scores

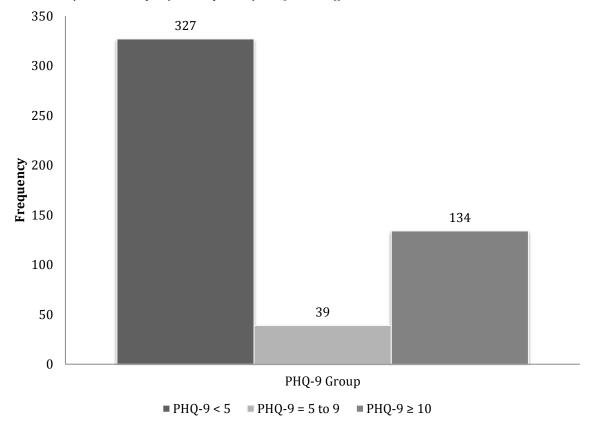


Figure 10

Ideal MHPN Workflow

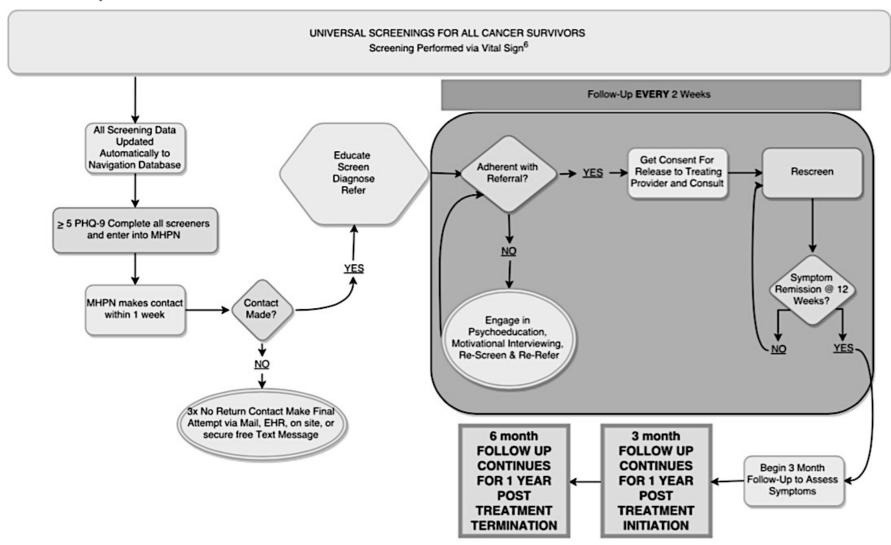


Table 1 Patient Demographics at Initial Screen and by Screening Result (Positive or Negative)

	A	ll Participants	Initial P	ositive Screen	Initial N	egative Screen			
Variable	N	$M \pm SD$	n	$M \pm SD$	n	$M \pm SD$	t	p	d
Age	500	53.71 ± 12.14	173	52.07 ± 11.31	327	54.58 ± 12.48	-2.21	.027	.21
Days Since Initial Cancer Diagnosis	500	293.84 ± 229.99	173	313.65 ± 227.24	327	283.36 ± 231.08	1.40	.161	.13
Demographic Variable	N	(%)	n (%)	Res.	n (%)	Res.	χ^2	p	V
Gender							0.01	.909	.01
Female	380	76.0%	132 (76.3)	0.1	248 (75.8)	-0.1			
Male	120	24.0%	41 (23.7)	-0.1	79 (24.2)	0.1			
Ethnicity ^A							0.93	.336	.04
Hispanic or Latinx	143	28.6%	45 (26.6)	-1.0	98 (30.0)	1.0			
Non-Hispanic or Latinx	344	68.8%	125 (72.3)	1.0	219 (67.0)	-1.0			
Other	3	0.6%	0 (0.0)		3 (0.9)				
Missing	10	2.0%	3 (1.7)		7 (2.1)				
Race							5.81	.121	.11
Black or African American	122	24.4%	50 (28.9)	1.6	72 (22.0)	-1.6			
White Hispanic	143	28.6%	45 (26.0)	-1.0	98 (30.0)	1.0			
White Non-Hispanic	207	41.4%	73 (42.2)	0.1	134 (41.0)	-0.1			
Other	15	3.0%	2 (1.2)	-1.8	13 (4.0)	1.8			
Missing	13	2.6%	3 (1.7)		10 (3.1)				

Bolded font indicate statistically significant results

Res. = Adjusted Residual. Adjusted Residuals with absolute values ≥ 2 signify significant differences between groups.

A = Within Ethnicity variable "Other" group was collapsed with Non-Hispanic or Latinx for Chi-Square analysis due to expected counts being <5.

Table 2

Participant Socioeconomic Ind							r Negative	?)	
		All cipants	Initial Posit Screen	ive	Initial Nega Screen				
		= 500	n = 17	3	$n = 32^{\circ}$				
	1 V -	- 300	n = 17		n = 32	1			
SES Variable	N	%	n (%)	Res.	n (%)	Res.	χ^2	p	V
Marital Status							15.83	.006	.15
Married	240	48.0%	70 (40.5)	-3.2	170 (52.0)	3.2			
Formerly Married	122	24.4%	53 (30.6)	2.0	69 (21.1)	-2.0			
Never Married	106	21.2%	46 (26.6)	1.8	60 (18.3)	-1.8			
Missing	32	6.4%	4 (2.3)		28 (8.6)				
Education ^A							9.75	.002	.17
No College or Advanced Degree	233	46.6%	111 (64.2)	3.1	122 (37.3)	-3.1			
College or Advanced Degree	105	21.0%	31 (17.9)	-3.1	74 (22.6)	3.1			
Missing	162	32.4%	31 (17.9)		131 (40.1)				
Employment							12.60	.006	.17
Employed	145	29.0%	46 (26.6)	-1.7	99 (30.3)	1.7			
Unemployed	121	24.2%	44 (25.4)	-0.2	77 (23.5)	0.2			
Retired	60	12.0%	17 (9.8)	-1.5	43 (13.1)	1.5			
On Disability	99	19.8%	51 (29.5)	3.4	48 (14.7)	-3.4			
Missing	75	15.0%	15 (8.7)		60 (18.3)				
Reported Household Income							8.12	.044	.22
<\$10,000	52	10.4%	31 (17.9)	0.5	21 (6.4)	-0.5			
\$10,000 to \$29,999	80	16.0%	40 (23.1)	-1.7	40 (12.2)	1.7			
\$30,000 to \$49,999	16	3.2%	14 (8.1)	2.6	2 (0.6)	-2.6			
\$50,000 or More	16	3.2%	8 (4.6)	-0.6	8 (2.4)	0.6			
Missing	336	67.2%	80 (46.2)		256 (78.3)				
Estimated Household Income ^B							1.99	.370	.06
Under \$30,000	109	21.8%	33 (19.1)	-1.1	76 (23.2)	1.1			
\$30,000 to \$49,999	140	28.0%	46 (26.6)	-0.5	94 (28.7)	0.5			
\$50,000 or More	251	50.2%	94 (54.3)	1.3	157 (48.0)	-1.3			
Percentage of FPL							1.47	.689	.06
Less Than 100% FPL	170	34.0%	65 (37.6)	-1.2	105 (32.1)	1.2			
100% to 150% FPL	85	17.0%	38 (22.0)	0.6	47 (14.4)	-0.6			
150% to 200% FPL	74	14.8%	33 (19.1)	0.6	41 (12.5)	-0.6			
Greater than 200% FPL	86	17.2%	37 (21.4)	0.3	49 (15.0)	-0.3			
Missing	85	17.0%	0	0	85	26			

Bolded font indicate statistically significant results

A "No College or Advanced Degree" included those with No High-School Degree and High-School Degree for Chi-Square due to expected cell counts <5.

^B Estimated Household Income is derived through Zip Code matched with Estimated Household Income based on 2015 Census Data.

Table 3 Patient Medical Status at Initial Screen and by Screening Result (Positive or Negative)

	All Part	icipants	Initial Pos Screen		Initial Neg Screen				
	N =	500	n = 17	3	n = 32	7			
Variable	N	%	n (%)	Res.	n (%)	Res.	χ^2	p	V
Pre-Existing Mental Illness							144.60	.000	.54
Yes	177	35.4%	123 (71.1)	12.0	54 (16.5)	-12.0			
No	318	63.6%	50 (28.9)	-12.0	268 (82.0)	12.0			
Missing	5	1.0%	0 (0.0)		5 (1.5)				
Enrolled in Survivorship							8.13	.004	.13
Yes	447	89.0%	164 (94.8)	2.9	283 (86.5)	-2.9			
No	53	11.0%	9 (5.2)	-2.9	44 (13.5)	2.9			
Genetic Carrier							0.02	.880	.01
Positive	21	4.2%	7 (4.0)	0.2	14 (4.3)	-0.2			
Negative	120	24.0%	38 (22.0)	-0.2	82 (25.1)	0.2			
Missing	359	71.8%	128 (74.0)		231 (70.6)				
Family History of Cancer							0.01	.913	.01
Yes	300	60.0%	102 (59.0)	-0.1	198 (60.6)	0.1			
No	139	27.8%	48 (27.7)	0.1	91 (27.8)	-0.1			
Missing	61	12.2%	23 (13.3)		38 (11.6)				

Bolded font indicate statistically significant results Res. = Adjusted Residual. Adjusted Residuals with absolute values ≥ 2 signify significant differences between groups.

Table 4

Patient Oncology Characteristics at Initial Screen and by Screening Result (Positive or Negative)

	All Pa	rticipants	Initial Pos Screen		Initial Negat Screens	ive			
	N:	= 500	n = 17.	3	n = 327				
Variable	N	%	n (%)	Res.	n (%)	Res.	χ^2	p	V
Active Cancer Treatment							1.36	.244	.05
Yes	174	34.8%	67 (38.7)	1.2	107 (32.7)	-1.2			
No	304	60.8%	101 (58.4)	-1.2	203 (62.1)	1.2			
Missing	22	4.4%	5 (2.9)		17 (5.2)				
Cancer Treatment Type ^A							3.42	.181	.09
Chemotherapy	128	25.6%	45 (26.0)	0.1	83 (25.4)	-0.1			
Other Treatment	46	9.2%	22 (12.7)	1.8	25 (7.7)	-1.8			
No Current Treatment	304	60.8%	100 (57.8)	-1.2	203 (62.1)	1.2			
Missing	22	4.4%	6 (3.4)		16 (4.9)				
Stage							2.99	.558	.09
0	14	2.8%	6 (3.5)	0.6	8 (2.4)	-0.6			
I	74	14.8%	23 (13.3)	-0.9	51 (15.6)	0.9			
II	75	15.0%	25 (14.5)	-0.5	50 (15.3)	0.5			
III	98	19.6%	41 (23.7)	1.5	57 (17.4)	-1.5			
IV	84	16.8%	28 (16.2)	-0.5	56 (17.1)	0.5			
Missing	155	31.0%	50 (28.9)		105 (32.1)				
Metastasis							0.19	.664	.02
Yes	88	17.6%	29 (16.8)	-0.4	59 (18.0)	0.4			
No	279	55.8%	99 (57.2)	0.4	180 (55.0)	-0.4			
Missing	133	26.6%	45 (26.0)		88 (26.9)				
Cancer Site							9.61	.383	.14
Breast	205	41.0%	65 (37.6)	-1.2	140 (42.8)	1.2			
Hematological and Bone/Soft Tissue	56	11.2%	15 (8.7)	-1.3	41 (12.5)	1.3			
Digestive	55	11.0%	17 (9.8)	-0.6	38 (11.6)	0.6			
Female Genital System	53	10.6%	25 (14.5)	2.0	28 (8.6)	-2.0			
Lung	36	7.2%	17 (9.8)	1.6	19 (5.8)	-1.6			
Male Genital System	28	5.6%	9 (5.2)	0.3	19 (5.8)	-0.3			
Head and Neck	21	4.2%	9 (5.2)	0.8	12 (3.7)	-0.8			
Urinary System	16	3.2%	6 (3.5)	0.2	10 (3.1)	-0.2			
Endocrine	11	2.2%	4 (2.3)	0.1	7 (2.1)	-0.1			
Skin	9	1.8%	3 (1.7)	-0.1	6 (1.8)	0.1			
Missing	10	2.0%	3 (1.7)		7 (2.1)				

Res. = Adjusted Residual. Adjusted Residuals with absolute values ≥ 2 signify significant differences between groups.
^A= Within Current Cancer Treatment Type all treatments other than Chemotherapy were collapsed into "Other Treatment" for Chi-Square analysis due to expected counts being <5.

Table 5

Patient Demographics by Group: Able to Navigate vs. Unable to Navigate

	Able to	o Navigate	Unable	e to Navigate			
Variable	n	$M \pm SD$	n	$M \pm SD$	t	р	d
Age	106	51.08 ± 1.11	67	53.64 ± 1.35	2.13	.147	.23
Days Since Initial Cancer Diagnosis	106	33.77 ± 22.74	67	281.82 ± 26.11	2.16	.143	.23
Initial PHQ-9 Score	106	14.21 ± 5.66	67	14.94 ± 5.37	0.85	.399	.13
Demographic Variable	n (%)	Res.	n (%)	Res.	χ^2	p	V
Gender					2.29	.131	.12
Female	85 (80.2)	1.5	47 (70.1)	-1.5			
Male	21 (23.7)	-1.5	20 (29.9)	1.5			
Ethnicity					0.99	.318	.08
Hispanic or Latinx	25 (23.6)	-1.0	20 (29.9)	1.0			
Non-Hispanic or Latinx	80 (75.5)	1.0	45 (67.2)	-1.0			
Missing	1 (0.9)		2 (3.0)				
Race					3.32	.146	.14
Black or African American	36 (34.0)	1.8	14 (20.9)	-1.8			
White Hispanic	25 (23.6)	-1.0	20 (29.9)	1.0			
White Non-Hispanic	43 (40.6)	-0.7	30 (44.8)	0.7			
Other	1 (0.9)	-0.3	1 (1.5)	0.3			
Missing	1 (0.9)		2 (3.0)				

Bolded font indicate statistically significant results

Table 6

Patient Socioeconomic Characteristics by Group: Able to Navigate vs. Unable to Navigate

	Able to Na	vigate	Unable to N	avigate			
	n = 10	6	n=6	7			
SES Variable	n (%)	Res.	n (%)	Res.	χ^2	p	V
Marital Status					3.81	.149	.15
Married	37 (34.9)	-2.0	33 (49.3)	2.0			
Formerly Married	36 (34.0)	1.2	17 (25.4)	-1.2			
Never Married	31 (29.2)	1.0	15 (22.4)	-1.0			
Missing	2 (1.9)		2 (3.0)				
Education ^A					0.95	.329	.08
No College or Advanced Degree	72 (67.9)	-1.0	39 (58.2)	1.0			
College or Advanced Degree	23 (21.7)	1.0	8 (11.9)	-1.0			
Missing	11 (10.4)		20				
Employment					0.61	.894	.06
Employed	29 (27.4)	-0.3	17 (25.4)	0.3			
Unemployed	27 (25.5)	-0.5	17 (25.4)	0.5			
Retired	12 (11.3)	0.6	5 (7.5)	-0.6			
On Disability	34 (32.1)	0.4	17 (25.4)	-0.4			
Missing	4 (3.8)		11 (16.4)				
Reported Household Income ^B					13.99	.001	.39
<\$10,000	16 (15.1)	-3.7	15 (22.4)	3.7			
\$10,000 to \$29,999	35 (33.0)	2.4	5 (7.5)	-2.4			
\$30,000 or More	19 (17.9)	1.4	3 (4.5)	-1.4			
Missing	36 (34.0)		23 (65.7)				
Estimated Household Income ^C					2.48	.289	.12
Under \$30,000	20 (18.9)	-0.1	13 (19.4)	0.1			
\$30,000 to \$49,999	24 (22.6)	-1.5	22 (32.8)	1.5			
\$50,000 or More	62 (58.5)	1.4	32 (47.8)	-1.4			
Percentage of Federal Poverty Level					2.36	.501	.12
Less Than 100% FPL	43 (37.6)	1.0	22 (32.8)	-1.0			
100% to 150% FPL	22 (22.0)	-0.5	16 (23.9)	0.5			
150% to 200% FPL	17 (19.1)	-1.3	16 (23.9)	1.3			
Greater than 200% FPL	24 (21.4)	0.5	13 (19.4)	-0.5			

A "No College or Advanced Degree" included those with No High-School Degree and High-School Degree for Chi-Square due to expected cell counts <5.

 $^{^{}B}$ = Within Reported Household Income variable \$50,000 or more was collapsed with \$30,000 to \$49,999 due to expected cell counts being <5

^C= Estimated Household Income is derived through Zip Code matched with Estimated Household Income through 2015 Census Data.

Table 7

Patient Medical History by Group: Able to Navigate vs. Unable to Navigate

	Able to Nav	igate	Unable to Na	avigate			
	n = 100	5	<i>n</i> = 67	1			
Variable	n (%)	Res.	n (%)	Res.	χ^2	p	V
Pre-Existing Mental Illness					0.02	.900	.01
Yes	75 (70.8)	-0.1	48 (71.6)	0.1			
No	31 (29.2)	0.1	19 (28.4)	-0.1			
Enrolled in Survivorship					0.13	.718	.03
Yes	101 (95.3)	0.4	63 (94.0)	-0.4			
No	5 (4.7)	-0.4	4 (6.0)	0.4			
Genetic Carrier					0.65	.420	.12
Positive	6 (5.7)	0.8	1 (1.5)	-0.8			
Negative	27 (25.5)	-0.8	11 (16.4)	0.8			
Missing	73 (68.9)		55 (82.1)				
Family History of Cancer					0.52	.473	.06
Yes	64 (60.4)	-0.7	38 (56.7)	0.7			
No	33 (31.1)	0.7	15 (22.4)	-0.7			
Missing	9 (8.5)	.1 1 1 .	14 (20.9)		1:00	1 4	

Table 8

Patient Oncology Characteristics by Group: Able to Navigate vs. Unable to Navigate

	Able to Na	avigate	Unable to N	avigate			
	n = 10	06	N=6	7			
Variable	n (%)	Res.	n (%)	Res.	χ^2	p	V
Active Cancer Treatment					0.23	.632	.04
Yes	40 (37.7)	-0.5	27 (40.3)	0.5			
No	64 (60.4)	0.5	37 (55.2)	-0.5			
Missing	2 (1.9)		3 (4.5)				
Current Cancer Treatment Type ^A					0.55	.758	.06
Chemotherapy	28 (26.4)	0.1	17 (25.4)	-0.1			
Other Treatment	72 (8.5)	-0.7	9 (13.4)	0.7			
No Current Treatment	63 (59.4)	0.4	37 (55.2)	-0.4			
Missing	6 (5.7)		4 (6.0)				
Metastasis					4.52	.034	.19
Yes	14 (13.2)	-2.1	15 (22.4)	2.1			
No	69 (65.1)	2.1	30 (44.8)	-2.1			
Missing	23 (21.7)		22 (32.8)				
Stage					12.32	.015	.32
0	4 (3.8)	0	2 (3.0)	0			
I	21 (19.8)	2.9	2 (3.0)	-2.9			
п	13 (12.3)	-1.6	12 (17.9)	1.6			
III	29 (27.4)	0.8	12 (17.9)	-0.8			
IV	14 (13.2)	-2.0	14 (20.9)	2.0			
Missing	25 (23.6)		25 (37.3)				
Cancer Site					13.56	.147	.28
Breast	46 (43.4)	1.8	19 (28.4)	-1.8			
Female Genital System	16 (15.1)	0.2	9 (13.4)	-0.2			
Hematological and Bone/Soft Tissue	11 (10.4)	0.9	4 (6.0)	-0.9			
Digestive	10 (9.4)	-0.3	7 (10.4)	0.3			
Lung	8 (7.5)	-1.4	9 (13.4)	1.4			
Urinary System	5 (4.7)	1.1	1 (1.5)	-1.1			
Male Genital System	4 (3.8)	-1.1	5 (7.5)	1.1			
Skin	2 (1.9)	0.2	1 (1.5)	-0.2			
Endocrine	2 (1.9)	-0.5	2 (3.0)	0.5			
Head and Neck	2 (1.9)	-2.6	7 (10.4)	2.6			
Missing	0 (0.0)		3 (4.5)				

Bolded font indicate statistically significant results

^A = Within Current Cancer Treatment Type all variables other than Chemotherapy were collapsed into "Other Treatment" for Chi-Square analysis due to expected counts being <5

Table 9

DSM-5 Diagnoses for Navigated Patients (n = 106)

	(0/)
Diagnosis	n (%)
Major Depressive Disorder	27 (25.5)
No Psychiatric Disorder	24 (22.6)
Adjustment Disorder	21 (19.8)
Co-morbid Major Depressive Disorder and Anxiety Disorder	14 (13.2)
Unspecified Depressive Disorder	8 (7.5)
Anxiety Disorder	4 (3.8)
Co-morbid Unspecified Depressive Disorder and Anxiety Disorder	2 (1.9)
Co-morbid Adjustment Disorder and Anxiety Disorder	2 (1.9)
Co-morbid Major Depressive Disorder and Dysthymic Disorder	1 (0.9)
Other ^A	3 (2.8)

A = Two patients met criteria for Bipolar Disorder. One patient met criteria for a psychotic disorder.

Table 10 $\label{eq:table_problem} \textit{Treatment Referrals for Navigated Patients (n = 106)}$

Referral	n (%)
Psychotherapy	54 (50.9)
Monitor and Re-Screen	26 (24.5)
Adjunctive Psychotherapy and Medication Management	16 (15.1)
Medication Management	5 (4.7)
Adjunctive Psychotherapy and Other	4 (3.8)
Other	1 (0.9)

Table 11

Cross-tabulation of Treatment Engagement by Navigation Status

_	Navigat	tion Status	<u>-</u>		
Engagement in Treatment	Navigation	No Navigation	χ^2	p	Cramer's V
Yes	71 (7.9)	4 (-7.9)	62.224**	.001	.6
No	35 (-7.9)	63 (7.9)			

^{**}p<.01

Table 12

Means of Symptom Reduction by Navigation Status

		95% Confidence Interval for Mean				_			
	n	Initial PHQ-9 Mean	Mean Symptom Reduction	SD	Std. Error	Lower Bound	Upper Bound	Min	Max
Navigated	106	14.21	-6.43	6.63	0.64	5.16	7.71	-11	19
Unable to Navigate	67	14.94	-1.46	3.87	0.47	0.52	2.41	-7	14
Total	173	14.49	-4.51	6.21	0.47	3.58	5.44	-11	19

Table 13

Analysis of Variance (ANOVA): Symptom Reduction by Navigation Status

	Sum of Squares	df	Mean Square	F	p	η^2
Between Groups	1014.54	1	1014.54	30.91	.000	.15
Within Groups	5612.69	171	32.82			
Total	6627.24	172				

Table 14

Correlation Table Assessing Multicollinearity in Hierarchical Regression

Variable	1	2	3	4	5	6	7
1. PHQ-9 Difference	-						
2. Reported Household Income	.06	-					
3. Metastasis	.15	.09	-				
4. Cancer Staging	.07	00	64	-			
5. Navigation Status	48	04	11	.08	-		
6. Treatment Engagement	52	09	18	.12	.69	-	
7. Number of Screens	.35	.05	.20	17	56	57	-

Table 15 Hierarchical Multiple Regression Predicting Reduction in Symptoms

		Symptom Reduction										
	Mod	del 1	Mod	del 2	Mod	iel 3	Mod	lel 4	Mod	lel 5	Mod	lel 6
Variable	В	β	В	β	В	β	В	β	В	β	В	β
Constant	5.01*		1.47		-7.01		2.77		5.71		5.25	
Reported Household income	0.48	0.06	0.37	0.04	0.25	0.03	0.12	0.1	-0.04	-0.01	-0.04	-0.01
Metastasis			2.13	0.14	4.82*	0.32	4.19	0.28	3.69	0.25	3.66	0.24
Cancer Stage					1.58	0.28	1.63*	0.29	1.64*	0.29	1.65*	0.29
Navigation Status							-6.37**	-0.47	-3.15	-0.23	-3.04	-0.23
Treatment Engagement									-4.04*	-0.35	-3.93*	-0.34
Number of PHQ-9 Screens											0.03	0.03
\mathbb{R}^2	.003		.023		.068		.288		.350		.350	
F	0.19		0.75		1.51		6.17**		6.46**		5.30**	
ΔR^2	.003		.020		.045		.220		.062		.000	
ΔF	0.19		1.30		3.00		18.84**		5.71*		0.04	

*p < .05, **p < .01Navigation Status: able to be navigated = 1, unable = 2
Treatment Engagement: Engaged = 1, No Engagement = 2

Table 16 Post-hoc Analysis: Patient Demographics by PHQ-9 Group

	(Group 1		Group 2	C	Group 3			
Variable	n	$M \pm SD$	n	$M \pm SD$	n	$M \pm SD$	F	р	η^2
Age	327	54.58 ± 12.48	39	54.9 ± 9.82	134	51.25 ± 11.62	3.84	.022	.02
Initial PHQ-9	327	$0.80 \pm .92$	39	6.79 ± 1.54	134	16.73 ± 4.08	2331.17	.000	.90
Days Since Initial Cancer Diagnosis	327	283.36 ± 231.08	39	315.75 ± 229.12	134	315.75 ± 229.98	1.01	.366	.00
Demographic Variable	n (%)	Res.	n (%)	Res.	n (%)	Res.	χ^2	р	V
Gender							0.93	.629	.04
Female	248 (75.8)	-0.1	32 (82.1)	0.9	100 (74.6)	-0.4			
Male	79 (24.2)	0.1	7 (17.9)	-0.9	34 (25.4)	0.4			
Ethnicity							3.47	.176	.07
Hispanic or Latinx	98 (30.0)	1.0	14 (35.9)	1.1	31 (23.1)	-1.7			
Non-Hispanic or Latinx	222 (67.0)	-1.0	24 (61.5)	-1.1	101 (75.4)	1.7			
Missing	7 (2.1)		1 (2.6)		2 (1.5)				
Race							10.53	.104	.10
Black or African American	72 (22.0)	-1.6	13 (33.3)	1.4	37 (27.6)	0.9			
White Hispanic	98 (30.0)	1.0	14 (35.9)	1.1	31 (23.1)	-1.7			
White Non-Hispanic	134 (41.0)	-0.1	11 (28.2)	-1.8	62 (46.3)	1.2			
Other	13 (4.0)	1.8	0 (0.0)	-1.1	2 (1.5)	-1.2			
Missing	10 (3.1)		1 (2.6)		2 (1.5)				

Bolded font indicate statistically significant results

Res. = Adjusted Residual. Adjusted Residuals with absolute values ≥ 2 signify significant differences between groups.

^A = Ethnicity variable "Other" includes Non-Hispanic or Latinx for Chi-Square analysis due to expected counts being <5.

Table 17 Post-hoc Analysis: Patient Socioeconomic Characteristics by PHQ-9 Group

	Group	1	Group	2	Group 3	3			
	n = 32	7	n = 39)	n = 134	1			
SES Variable	n (%)	Res.	n (%)	Res.	n (%)	Res.	χ^2	p	V
Marital Status							15.83	.003	.13
Married	170 (52.0)	3.2	16 (41.0)	-0.9	54 (40.3)	-2.9			
Formerly Married	69 (21.1)	-2.0	15 (38.5)	2.2	38 (28.4)	0.8			
Never Married	60 (18.3)	-1.8	5 (12.8)	-1.3	41 (30.6)	2.7			
Missing	28 (8.6)		3 (7.7)		1 (0.7)				
Education ^A							10.65	.005	.18
No College or Advanced Degree	122 (37.3)	-3.1	28 (71.8)	2.1	83 (61.9)	2.0			
College or Advanced Degree	74 (22.6)	3.1	5 (12.8)	-2.1	26 (19.4)	-2.0			
Missing	131 (40.1)		6 (15.4)		25 (18.7)				
Employment							14.86	.021	.13
Employed	99 (30.3)	1.7	10 (25.6)	-0.5	36 (26.9)	-1.5			
Unemployed	77 (23.5)	0.2	6 (15.4)	-1.4	38 (2.4)	0.6			
Retired	43 (13.1)	1.5	5 (12.8)	0.2	12 (9.0)	-1.7			
On Disability	48 (14.7)	-3.4	12 (30.8)	1.8	39 (29.1)	2.5			
Missing	60 (18.3)		6 (15.4)		9 (6.7)				
Reported Household Income ^B							6.53	.163	.14
<\$10,000	21 (6.4)	-0.5	5 (12.8)	-1.0	26 (19.4)	1.2			
\$10,000 to \$29,999	40 (12.2)	1.7	13 (33.3)	1.0	27 (20.1)	-2.4			
\$30,000 or More	10 (3.1)	-1.5	4 (10.3)	-0.2	18 (13.4)	1.6			
Missing	256 (78.3)		17 (43.6)		63 (47.0)				
Estimated Household Income ^C							3.15	.532	.06
Under \$30,000	76 (23.2)	1.1	7 (17.9)	-0.6	26 (19.4)	-0.8			
\$30,000 to \$49,999	94 (28.7)	0.5	13 (33.3)	0.8	33 (24.6)	-1.0			
\$50,000 or More	157 (48.0)	-1.3	19 (48.7)	-0.2	75 (56.0)	1.6			
Percentage of Federal Poverty Level							4.84	.564	.08
Less Than 100% FPL	105 (32.1)	1.2	16 (41.0)	0.0	49 (36.6)	-1.3			
100% to 150% FPL	47 (14.4)	-0.6	5 (12.8)	-1.2	33 (24.6)	1.4			
150% to 200% FPL	41 (12.5)	-0.6	7 (17.9)	0.0	26 (19.4)	0.6			
Greater than 200% FPL	49 (15.0)	-0.3	11 (28.2)	1.2	26 (19.4)	-0.5			
Missing	85 (26.0)		0 (0.0)		0 (0.0)				

Bolded font indicate statistically significant results

groups. A= Within Education variable No High-School Degree collapsed with High-School Degree for Chi-Square due to expected cell counts < 5.

^B = Within Reported Household Income variable \$50,000 or more was collapsed with \$30,000 to \$49,999 due to expected cell

^C= Estimated Household Income is derived through Zip Code matched with Estimated Household Income through 2015 Census Data.

Table 18 Post-hoc Analysis: Patient Medical History by PHQ-9 Group

	Group	1	Group	2	Group	3			
	n = 327	7	n=3	9	n = 134				
Variable	n (%)	Res.	n (%)	Res.	n (%)	Res.	χ^2	p	V
Pre-Existing Mental Illness							146.60	.000	.54
Yes	54 (16.5)	-12.0	24 (61.5)	3.5	99 (73.9)	10.8			
No	268 (82.0)	12.0	15 (38.5)	-3.5	35 (26.1)	-10.8			
Missing	5 (1.5)		0 (0.0)		0 (0.0)				
Enrolled in Survivorship							9.49	.009	.14
Yes	283 (86.5)	-2.9	35 (89.7)	0.1	129 (96.3)	3.0			
No	44 (13.5)	2.9	4 (10.3)	-0.1	5 (3.7)	-3.0			
Genetic Carrier							0.7	.706	.07
Positive	14 (4.3)	-0.2	1 (20.6)	-0.7	6 (4.5)	0.6			
Negative	82 (25.1)	0.2	11 (28.2)	0.7	27 (20.1)	-0.6			
Missing	231 (70.6)		27 (69.2)		101 (24.6)				
Family History of Cancer							0.12	.941	.02
Yes	198 (60.6)	0.1	23 (59.0)	-0.3	79 (59.0)	0.1			
No	91 (27.8)	-0.1	12 (30.8)	0.3	36 (26.9)	-0.1			
Missing	38 (11.6)		4 (10.3)		19 (14.2)				

Bolded font indicate statistically significant results Res. = Adjusted Residual. Adjusted Residuals with absolute values ≥ 2 signify significant differences between groups.

Table 19 Participant Oncology Characteristics by PHQ-9 Group

	Group	1	Group	2	Group	3			
	n = 32	7	n = 3	9	n = 13	34			
Variable	n (%)	Res.	n (%)	Res.	n (%)	Res.	χ^2	p	V
Active Cancer Treatment							1.55	.461	.06
Yes	107 (32.7)	-1.2	14 (35.9)	0.1	53 (39.6)	1.2			
No	203 (62.1)	1.2	24 (61.5)	-0.1	77 (57.5)	-1.2			
Missing	17 (5.2)		1 (2.6)		4 (2.6)				
Current Treatment Type ^A							4.41	.354	.07
Chemotherapy	83 (25.4)	-0.1	8 (20.5)	-0.7	37 (27.6)	0.5			
Other Treatment	25 (7.6)	-1.8	6 (15.4)	1.4	16 (11.9)	1.1			
No Current Treatment	203 (62.1)	1.2	23 (59.0)	-0.2	77 (57.5)	-1.2			
Missing	16 (4.9)		2 (5.1)		4 (3.0)				
Metastasis							1.14	.567	.06
Yes	59 (18.0)	0.4	4 (10.3)	-1.1	25 (18.7)	0.1			
No	180 (55.0)	-0.4	22 (56.4)	1.1	77 (57.5)	-0.1			
Missing	88 (26.9)		13 (33.3)		32 (23.9)				
Stage							6.65	.575	.10
0	8 (2.4)	-0.6	1 (2.6)	-0.1	5 (3.7)	0.6			
I	51 (15.6)	0.9	8 (20.5)	1.2	15 (11.2)	-1.7			
II	50 (15.3)	0.5	6 (15.4)	0.2	19 (14.2)	-0.6			
III	57 (17.4)	-1.5	7 (17.9)	-0.2	34 (25.4)	1.7			
IV	56 (17.1)	0.5	4 (10.3)	-1.1	24 (17.9)	0.1			
Missing	105 (32.1)		13 (33.3)		37 (27.6)				
Cancer Site							21.81	.241	.15
Breast	140 (42.8)	1.2	15 (38.5)	-0.4	50 (37.3)	-1.0			
Digestive	38 (11.6)	0.6	3 (7.7)	-0.7	14 (10.4)	-2.0			
Lung	19 (5.8)	-1.6	4 (10.3)	0.7	13 (9.7)	1.3			
Urinary System	10 (3.1)	-0.2	0 (0.0)	-1.2	6 (4.5)	1.0			
Female Genital System	28 (8.6)	-2.0	6 (15.4)	1.0	19 (14.2)	1.6			
Male Genital System	19 (5.8)	0.3	1 (2.6)	-0.9	8 (6.0)	0.2			
Head and Neck	12 (3.7)	-0.8	5 (12.8)	2.7	4 (3.0)	-0.8			
Hematological and Bone	41 (12.5)	1.3	3 (7.7)	-0.8	12 (9.0)	-1.0			
Skin	6 (1.8)	0.1	0 (0.0)	-0.9	3 (2.2)	0.5			
Endocrine	7 (2.1)	-0.1	2 (5.1)	1.3	2 (1.5)	-0.6			
Missing Res. = Adjusted Residua	7 (2.1)	2.1	0 (0.0)		3 (2.2)				

groups.

A = Within Current Cancer Treatment Type all variables other than Chemotherapy were collapsed into "Other Treatment" for Chi-Square analysis due to expected counts being <5

Table 20

One-Way Analysis of Variance (ANOVA) of Mean Age at Screening by PHQ-9 Group

	Sum of Squares	df	Mean Square	F	p
Between Groups	1118.20	2	559.10	3.84	0.022*
Within Groups	72359.9	497	145.59		
Total	73478.10	499			

Note * = P < .05

Table 21

Multiple Comparisons

Dependent Varia	able: Age at Screening							
	(I) PHQ9 Group	(J) PHQ9 Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval		
						Lower Bound	Upper Bound	
Tukey HSD	Group 1	Group 2	-0.313	2.044	0.987	-5.12	4.49	
		Group 3	3.338*	1.238	0.02	0.43	6.25	
	Group 2	Group 1	0.313	2.044	0.987	-4.49	5.12	
		Group 3	3.651	2.195	0.221	-1.51	8.81	
	Group 3	Group 1	-3.338*	1.238	0.02	-6.25	-0.43	
		Group 2	-3.651	2.195	0.221	-8.81	1.51	
Games-Howell	Group 1	Group 2	-0.313	1.717	0.982	-4.45	3.83	
		Group 3	3.338*	1.218	0.018	0.47	6.21	
	Group 2	Group 1	0.313	1.717	0.982	-3.83	4.45	
		Group 3	3.651	1.866	0.13	-0.81	8.12	
	Group 3	Group 1	-3.338*	1.218	0.018	-6.21	-0.47	
		Group 2	-3.651	1.866	0.13	-8.12	0.81	

^{*} The mean difference is significant at the 0.05 level.

APPENDIX A VitalSign⁶ Component Measures

Patient Adherence Questionnaire

The Patient Adherence Questionnaire (PAQ) (Warden et al., 2014) is a two-item, self-report inventory that assesses patient adherence to the antidepressant treatment being prescribed. Patients who do not take their prescribed medications more than 70% of the time are considered non-adherent. For these patients, the instrument asks them to list the reasons for non-adherence.

Frequency, Intensity, and Burden of Side Effects Rating Scale

The Frequency, Intensity, and Burden Side Effects Rating Scale (FIBSER), developed by Wisniewski et al. (Wisniewski, 2006), is a three-item, self-report inventory that assesses side effects to treatments. It measures frequency of side effects, intensity of side effects, and functional impairment of side effects reported. VS⁶ scores the measure and reports the degree of frequency, intensity, and burden of side effects to the provider. Based on the score, side effects are categorized as acceptable, requires attention, or unacceptable.

Generalized Anxiety Disorder 7-item

The Generalized Anxiety Disorder 7-item (GAD-7), developed by Spitzer et al. (Spitzer, 2006) assesses symptoms in seven domains of generalized anxiety, with an additional question assessing functional impairment, on a three-point Likert Scale asking patients to rate how often they have experienced the seven symptoms of GAD over the past two weeks (not at all = 0, several days, 1, more than half the days = 2, nearly every day = 3). Scores of 5-9 indicate mild symptom severity, 10-14 indicates moderate symptom severity, and scores ≥15 indicate severe symptoms of GAD. The GAD-7 has been recommended to evaluate anxiety in cancer patients (Lazenby et al., 2015).

Pain Frequency, Intensity, and Burden Scale

The Pain Frequency, Intensity, and Burden Scale (P-FIBS), developed by dela Cruz and colleagues (dela Cruz et al., 2014), is a brief, self-administered measurement of pain frequency, intensity, and burden and is comprised of four items that are rated on nine-point scales. The score is computed by summing the responses to each item. This measure provides assessment of both pain levels and current use of pain management interventions (dela Cruz et al., 2014).

Alcohol and Drug Use Screen

The Alcohol and Drug Screen is comprised of two screening items: one for alcohol use and one for substance/drug use. Both ask about use during the past year and are designed to screen for current use patterns that might impact depression treatment.

APPENDIX B Sensitivity Analysis

Due to this study's design, there was a lack of control over time points and frequencies of follow-up with PHQ-9 screens. This lack of control was particularly impactful to the sample of patients that were unable to be navigated as it resulted in a majority n=37 (55.2%) of those patients missing follow-up measures. A sensitivity analysis was performed to assess the impact of this missing data in an effort to identify an appropriate method of replacing missing PHQ-9 follow-up data.

Missing PHQ-9 outcome data was accounted for using the following six different methods: (1) last observation carried forward (LOCF) (i.e., this assumes patients had no change in symptom severity between first and last screen); (2) Imputed missing data using the mean value from all patients who were observed to have a reduction in symptoms (i.e., this assumes patients with missing data experienced the same reduction in symptoms as the mean for the entire sample) (n = 102, M = -8.79, SD = 4.78); (3) Imputed missing data using the mean value by group who were observed to have reduction in symptoms (i.e., this assumes that patients with missing data experienced the same reduction in symptoms as others in the group) (n = 18, M = -18, M6.78, SD = 4.07; (4) Imputed missing data using the mean value from all patients who were observed to have an increase in symptom severity (i.e., this assumes that patients with missing data experienced the same mean increase in symptom severity for the sample) (n = 19, M = 4.00,SD = 2.71; (5) Imputed missing data using the mean value from unable to navigate patients who were observed to have an increase in symptom severity (i.e., this assumes that patients with missing data experienced the same mean increase in symptom severity as others in the group) (n = 4, M = 4.5, SD = 2.09); and (6) Excluded patients with missing data.

Using LOCF (method #1) resulted in patients who were unable to be navigated having a mean reduction in symptoms of M =-1.46, SD = 3.87. Imputation of the mean for all patients observed to have a reduction in symptoms (method #2) resulted in M = -6.80, SD = 4.25 for patients who were unable to be navigated. Imputation of the mean for patients observed to have a reduction in symptoms in the unable to navigate cohort (method #3) resulted in an overall mean symptom reduction for the group of M = -5.59, SD = 3.77. Imputation of the mean for all patients observed to have an increase in symptom severity (method #4) resulted in M = 0.84, SD = 5.21. Imputations of the mean for patients in the unable to navigate cohort observed to have an increase in symptom severity (method #5) resulted in an overall mean symptom reduction for the group of M = 1.13, SD = 5.40. Excluding patients with missing data (method #6) resulted in patients who were unable to be navigated having a mean reduction in symptoms of M = -3.38, SD = 5.35).

Prior to running the one-way analysis of variance all assumptions were tested and met. A one-way analysis of variance (ANOVA) using the difference between last and first screen as the dependent variable and navigation status as the independent variable was then run using each method of missing data management. There were statistically significant differences when the last available data point was used to impute missing data (method #1) $F(1, 171) = 30.91, p < .001, \eta^2 = .15$; when using imputed data from all patients observed to have an increase in symptom severity (method #4) $F(1,171) = 62.30, p > .001, \eta^2 = .27$; when missing data was imputed for patients who demonstrated symptom increase within the unable to navigate cohort (method #5) $F(1,171) = 65.79, p < .001, \eta^2 = .28$; and when patients with missing data were excluded (method #6) $F(1,134) = 5.41, p < .05, \eta^2 = .04$. There were no statistically significant differences observed when imputing means from all patients who demonstrated a reduction in symptoms

(method #2) (F = 0.00, p = .003) or when imputing from the cohort of patients who where unable to be navigated and demonstrated a reduction in depression symptoms (method #3) (F = 1.94, p = .166).

There was not convergence for all factors of the sensitivity analysis. We will now consider each imputation method. Methods two and four involved using imputed data based on the entire sample. Over 50% of patients who were unable to be navigated had missing data. Therefore, using the mean difference in first and last screen from the entire study sample is heavily influenced by patients that were able to be navigated. This is illustrated by the finding that navigated patients would account for 82.3% and 79.0% of data used to calculate means for symptom reduction (method #2) and symptom increase (method #4), respectively.

Methods three and five involve using imputed data based on the unable to be navigated cohort. Of patients who were unable to be navigated and had available data points for use in the sensitivity analysis, it was observed that 18 patients had demonstrated reduction in depression symptoms, 4 that had an increase in symptoms, and 7 whose symptom severity stayed the same.

In regards to method three, it was revealed that 10 of the 18 patients who demonstrated a reduction in symptoms were previously engaged in therapeutic services prior to the implementation of the MH-SCAN program. Therefore, in using the mean of these 18 patients, the outcome measures are likely more representative of patients who were able to be navigated, as results of the study revealed that patients from this cohort were more likely to engage in referred treatment for depression.

In regards to method five, it is likely not a valid representation of the sample by using the mean for only four patients to impute the 37 instances of missing data as this likely artificially inflates the scores in the direction of an increase in symptom severity.

This leaves two final options for use in analyzing aim 4: (method #1) last observation carried forward and (method #6) excluding patients with missing outcome data. Carrying the last available data endpoint forward is the most conservative approach to missing data (Gambi et al., 2005), while excluding patients with missing data limits the generalizability of the results and possibly introduces bias (Robert M. Hamer & Pippa M. Simpson 2009).

When excluding patients with missing data in this study, it is revealed that those that do not have missing data are by definition receiving some form of treatment. If patients were not contacted by a patient navigator for follow-up after an initial positive PHQ-9, they were screened after coming into UTSW MCI for a clinical service. The Survivorship Program at UTSW MCI offers cancer survivors free services such as psychotherapy, exercise groups, or nutritional consultations. If a patient in the unable to navigate group has a follow-up screen it is because they are enrolled in one of these programs. Research has revealed that both exercise (Chen, Tsai, Wu, Lin, & Lin, 2015) and nutritional consultations (Numakawa et al., 2014) are associated with a reduction in symptoms of depression. Therefore, excluding patients with missing data likely biases the data set. As such, the data suggests that using last observation carried forward (LOCF) is likely most representative of patients that were unable to be navigated.

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