Predicting Patient Preferences for Individual Meaning-Centered Psychotherapy and the Impact of Matching to Preference on Treatment Engagement and Therapeutic Alliance

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Allison Marziliano

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Allison Marziliano

We, the dissertation committee for the above candidate for the

Doctor of Philosophy Degree, hereby recommend

acceptance of this dissertation.

Anne Moyer- Dissertation Advisor
Associate Professor, Department of Psychology

Antonio Freitas- Chairperson of Defense
Associate Professor, Department of Psychology

Daniel O'Leary- Committee Member
Distinguished Professor, Department of Psychology

Hayley Pessin- Committee Member
Clinical Psychology, Memorial Sloan Kettering Cancer Center

This dissertation is accepted by the Graduate School

Charles Taber

Dean of the Graduate School

Abstract of the Dissertation

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The current study aims to identify whether demographic, disease-related, psychological, and spirituality/religiosity variables predict patients' preference for Individual Meaning-Centered Psychotherapy (IMCP) compared to Individual Supportive Psychotherapy (ISP). In addition, this study aims to examine whether assigning patients to their preferred therapy arm impacts both their engagement with their assigned treatment in a randomized controlled trial (RCT) and their therapeutic alliance mid-way through treatment. Data for these analyses were drawn from a RCT comparing IMCP, ISP, and Enhanced Usual Care (EUC) in a sample of patients with advanced cancer. Results demonstrated that patients with higher levels of education were more likely to endorse IMCP as their preference compared to ISP. All other predictors (age, cancer type, depression, anxiety, hopelessness, desire for hastened death, spirituality and religiosity) did not significantly predict preference for IMCP. Matching to treatment did not significantly impact engagement with the treatment, as measured by number of sessions attended. However, patients who were matched to their preferred treatment scored higher on the Working Alliance Inventory than patients who were mismatched to their preferred treatment. This difference was significant only in the case of those who preferred IMCP; patients who preferred and were assigned to IMCP scored significantly higher on the Working Alliance Inventory than patients who preferred IMCP but were assigned to ISP. Possible reasons include that IMCP is a novel therapy that could not be found elsewhere. These results imply that, when comparing novel therapies with standard treatments, as is often the case in RCTs, patients who prefer the novel treatment but do not receive it may feel particularly disappointed that their only opportunity for an innovative therapy was unsuccessful, hindering their therapeutic alliance and potentially their outcomes.

Keywords: patient preferences, meaning-centered, matching, attrition, alliance

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Predicting Patient Preferences for Individual Meaning-Centered Psychotherapy and the Impact of Matching to Preference on Treatment Engagement and Therapeutic Alliance

Different treatments are compared and contrasted in randomized controlled trials (RCTs), widely considered to be the "gold standard" in evaluating the efficacy of medical and psychological treatments (Chambless & Hollon, 1998; Lohr & Carey, 1999; Pocock, 1983). The key component of a RCT is randomization, whereby study participants are assigned to different treatment conditions at random as a means of balancing potentially confounding variables across groups prior to study manipulation (Sacks, Chalmers, & Smith, 1982). Although not typically the focus of RCTs designed to investigate the efficacy of contrasting treatments, this study design also provides the opportunity to investigate the dynamics of randomly assigning patients to treatments they have or have not expressed a preference to participate in.

Treatment preference may be defined as the "desirability of a treatment, process or treatment choice" (Krahn & Naglie, 2008, p. 436). More broadly, preferences refer to "patient perspectives, beliefs, expectations and goals for health and life, and to the process that individuals use in considering the potential benefits, harms and costs and inconveniences of the management options in relation to one another" (Montori, Brito, & Murad, 2013, p. 2503). Research has provided concrete illustrations for the ways in which preferences for medical treatment to combat physical illnesses vary according to factors both internal and external to the patient. For example, for a young individual with a fatal cancer in a curable stage, an aggressive treatment aimed at survival, irrespective of the burden it may cause, may be the preference; by contrast, for an elderly, frail individual diagnosed with mild diabetes, treatment aimed at improving quality of life, rather than treatment aimed at prolonging life, may be the preference (Montori et al., 2013). Stated another way, "an effective but toxic chemotherapeutic regimen is the treatment one patient with cancer can and will take, another patient can take but will not, and yet another patient could not take even if wanted" (Montori et al., 2013, p. 2503). Thus, research suggests a critical role of patient preferences and how such preferences interact with internal and external variables to influence medical decision making and medical care, in the context of physical illness and particularly at end of life (Wright et al., 2010).

Whereas patients' preferences for a medical treatment to combat physical illness may vary, studies indicate that, when given an option, most patients prefer psychotherapy over pharmacological treatment as the treatment of choice to combat various mental illnesses. In a systematic review of treatment preferences of survivors of traumatic events, 18 of 19 quantitative studies indicated overall preference for psychotherapy over medication. Furthermore, in seven of these studies, greater than 80% of the sample preferred psychotherapy to medication, whereas a maximum of 36% preferred medication to psychotherapy (Simiola, Neilson, Thompson, & Cook, 2015). A meta-analysis of treatment preferences of patients with various psychiatric disorders indicated a significant three-fold preference for psychological treatment relative to medication (McHugh, Whitton, Peckham, Welge, & Otto, 2013). Similar results have been found in studies of primary care patients (Raue, Schulberg, Heo, Klimstra, & Bruce, 2009).

When studying patients' preferences in regard to treatment for mental health, then, the question is less often "psychotherapy or pharmacotherapy," as there is a great deal of empirical support devoted to this topic. By contrast, the question "of the myriad of diverse psychological interventions available, which do patients prefer?" is understudied and warrants further attention (Sherman et al., 2007). Preferences for various types of psychotherapy as opposed to different types of medical treatments may be even more important because psychotherapy often requires more patient engagement and cooperation, and because expectations about efficacy may be even more powerful in influencing engagement and potentially outcomes. It is evident that a "one size fits all" approach to treating mental disorders or enriching mental health is unsatisfactory, as a single treatment effective or superior for all individuals does not exist (Moyer, Finney, Elworth, & Kraemer, 2001; Simiola et al., 2015). In response, several authors have encouraged increasing research attention to understanding patient preferences (Feeny, Zoellner, Mavissakalian, & Roy-Byrne, 2009; Howard & Thornicroft, 2006; Moyer et al., 2001; Moyer, Knapp-Oliver, Sohl, Schnieder, & Floyd, 2009; Sommers et al., 2008).

Understanding patient preferences for one psychological treatment over another is critical for several reasons. First, although there is noteworthy evidence to the contrary (Floyd & Moyer, 2010; King et al., 2005), there is considerable evidence to suggest that patients who are assigned to their preferred treatment arm in psychotherapy trials are more likely to remain in the study than those assigned to arms they did not prefer. In a meta-analysis examining impact of preference on outcomes in various disorders, patients who were assigned to their preferred psychological treatment were 50% less likely to drop out of the study than those patients who were mismatched to their preferred treatment arm (Swift & Callahan, 2009). Of note, this meta-analysis included studies of psychological treatments and mixed psychological and pharmacological treatments, and excluded studies of pharmacological treatments only. Potential explanations for this finding include that patients may resent not receiving their preferred treatment, thereby leading to an overall negative attitude about the trial or disappointment, termed "resentful demoralization," (Bowling & Rowe, 2005; Bradley, 1996) and subsequent non-adherence to the study. Although understanding how treatment preference impacts adherence, attrition, and dropout is important in the realm of research, it is even more so clinically, as patients who are treated by their therapist with a psychological treatment they prefer may be more likely to continue to attend their therapy sessions than those who are treated with a non-preferred treatment, thereby allowing them the potential to reap the full benefits of that particular approach.

In a similar vein, research to understand patient preferences is a worthwhile endeavor, as there is empirical support for matching patients to their preferred treatment in order to lead to positive clinical outcomes. In a study in which patients with major depressive disorder were offered the options of randomization or their preferred treatment, those who willingly selected counseling fared better clinically than those who were randomized to counseling (Chilvers et al., 2001). In another study of 106 patients with major depressive disorder, mismatch to the preferred treatment arm was correlated with a less positive working alliance with the clinician (Kwan, Dimidjian, & Rizvi, 2010). Other studies (George & Robinson, 2010; Mergl et al., 2011; Swift & Callahan, 2009) have demonstrated a similar positive effect of matching patients to their preferred treatment, and some researchers (Howard & Thornicroft, 2006) have stated that matching may lead to better clinical outcomes than mismatching regardless of the efficacy of the intervention involved. Nevertheless, there is a plethora of evidence to discredit or refute these findings (McKay, Alterman, McLellan, Snider, & O'Brien, 1995; Moyer et al., 2001; Raue et al., 2009; Ward et al., 2000), creating an inconsistent picture and further illustrating the need for additional research to understand patient preferences.

Understanding patient preferences, whether it be in the context of a psychotherapy trial or a clinical life-altering treatment, is a critical first step to improving patient-provider communication (Patel & Bakken, 2010) and engaging in decision-making that is the result of collaboration among physicians, patients, and their families, termed *shared decision-making*. Shared decision-making is esteemed as the ideal model of communication in the context of serious illnesses in which there is not a clear optimal treatment but rather competing options for treatment, each with their own risks (Braddock, Fihn, Levinson, Jonsen, & Pearlman, 1997; Whitney, McGuire, & McCullough, 2004). In a survey study of cancer survivors, the majority (88%) of participants selected their preferred role as either active or collaborative in regard to their contribution to decision-making during their previous cancer care. Participants whose preferred roles were in accordance with their actual roles reported higher physical quality of life and vitality, better overall mood, and less confusion, fatigue, and anger (Atherton et al., 2013). This research suggests that patients may benefit when their physicians are aware of their preferences regarding care and treatment, and when knowledge of these preferences leads to shared decision-making. Applying this concept to different psychological treatments in a clinical setting indicates that patients may benefit when their therapists encourage the process of selecting a psychological treatment to take the form of a dialogue between clinician and patient, validating the importance of patient preferences.

Despite this evidence, there is research to suggest that shared decision-making is an anomaly in the realm of healthcare (Tulsky, Chesney, & Lo, 1995; Tulsky, Fischer, Rose, & Arnold, 1998; White, Braddock, Bereknyei, & Curtis, 2007), with one study reporting that merely 39% of patients with advanced cancer engaged in a discussion with their physician about their preferences with regard to treatment decision-making (Mack, Weeks, Wright, Block, & Prigerson, 2010). Fortunately, some countries such as Great Britain, Australia, and Germany, are prioritizing studying the ways in which to incorporate patient preferences into health policy decision-making (Muhlbacher & Juhnke, 2013).

Other factors driving research on patient preferences highlight the practical benefits such research may confer, including conserving time and finances. Psychologists and psychiatrists, for example, are increasingly battling patient overload and time constraints. Knowledge of their patients' preferences for different treatment options may be critical in assisting clinicians with which treatments to prioritize when deciding to incorporate new interventions into their burgeoning practices. Understanding preferences may further conserve time during intake or treatment sessions by leading to more-tailored discussions between patients and clinicians (Simiola et al., 2015). On a grander scale, knowledge of patient preferences may increase efficiency of marketing treatments to different populations (Sherman et al., 2007), preventing a situation in which a particular treatment is offered to a demographic that has been historically disinterested in said treatment.

In addition to conserving time, other authors have pointed to the possibility of reducing healthcare expenses through initially gaining a better understanding of which therapies patients prefer to engage in, rather than blindly attempting several treatments that may be of little or no interest to the patient prior to settling on a therapy the patient prefers (Downey, Au, Curtis, & Engelberg, 2013). Still others (Brazier, Dixon, & Ratcliffe, 2009) state that research on treatment preferences will facilitate estimating the cost-effectiveness of innovative psychological treatments, which is increasingly becoming a requirement stipulated by reimbursement agencies.

The preceding paragraphs emphasize the significance of understanding patient preferences for various psychological treatments. From this logically follows a discussion of the components of different psychological treatments and, for the purposes of this study, a discussion of which variables distinguish one of the focal psychotherapeutic interventions studied in the current project--namely, Individual Meaning-Centered Psychotherapy (IMCP)--from the rest.

Patients with terminal illnesses such as metastatic cancer have often reported feelings of meaninglessness, or the perception of a lack of meaning, purpose, and value in life (Morita, Sakaguchi, Hirai, Tsuneto, & Shima, 2004). A terminal diagnosis, in many cases, is accompanied by fear and angst, which may contribute to hopelessness, existential crises, and, in some cases, a desire for hastened death (Holland et al., 2015). Indeed, clinicians and researchers are increasingly pointing out that treating patients at the end of life involves more than merely treating their pain and physical symptoms. Rather, comprehensive end-of-life care should tend to patients' psychiatric, psychosocial, existential, and spiritual concerns (Holland et al., 2015), as well as aim to nurture patients' views of meaning (Morita et al., 2004).

In response to this call, there has been a surge of meaning-focused therapies, particularly for patients with terminal cancer. For example, some research has demonstrated the efficacy of a meaning-making intervention that incorporates an exercise to build meaning for the cancer experience and maintain meaning in life. This study found that participants randomized to the meaning-making intervention exhibited increased self-esteem, self-efficacy, and optimism, which, in turn, increased their meaning, despite their receiving chemotherapy (Lee, Cohen, Edgar, Laizner, & Gagnon, 2006). Similar results were found for patients who were newly diagnosed, completing treatment, or experiencing a recurrence of breast or colorectal cancer who received this meaning-making intervention (Lee et al., 2006). At the post-intervention time point, these patients had an increase in their self-esteem as well as greater security when dealing with the uncertain aspects of the cancer experience (Lee et al., 2006). Another meaning-focused therapy, Meaningful Life Therapy, emphasizes an active fight against cancer while engaging in constructive activities (Ishu, 1990). The rise in meaning-therapies has exhibited such a great degree of prominence that, in the *Handbook of Oncology Social Work*, there is a chapter aimed at reviewing meaning-focused therapies in Australia. These therapies have the intent of encouraging meaning and purpose in life and in relating to others amidst suffering.

In the proposed study, the focus is on IMCP, a meaning therapy developed by Dr. William Breitbart, the Chair of the Department of Psychiatry and Behavioral Sciences at Memorial Sloan Kettering Cancer Center in New York City, New York. IMCP is inspired by the works of Dr. Viktor Frankl, an Austrian psychiatrist who lived during the time of the Holocaust, and informed by Dr. Irvin Yalom, an American existential psychiatrist. This brief intervention utilizes didactics and experiential exercises to enhance meaning and purpose in the life of patients with advanced cancer despite their being faced with a terminal illness. The therapy is collaborative in that patients and clinicians strive to, through exploring sources of meaning, facilitate a deeper understanding of the importance of patients' creating, enhancing, and sustaining meaning in life. These sources of meaning, such as attitude, beauty and humor, can be drawn on during a particularly difficult time, such as when battling a cancer diagnosis, to mitigate the negative feelings created by the event (Holland et al., 2015). IMCP has been examined in several trials with patients with advanced cancer in both group and individual formats, and the literature suggests that it is effective in improving spiritual well-being, a sense of meaning in life, and quality of life, and reducing anxiety, desire for hastened death, depression, hopelessness, and symptom burden (Breitbart et al., 2010; Breitbart et al., 2012; Breitbart et al., 2015).

Given its proven efficacy in prior research studies, providing IMCP as a clinical service may be highly useful for many patients. However, in order to maximize its utility, a detailed profile for which type of patient would prefer this therapy is critical. Such a profile, consisting of demographic, disease-related, psychological and spiritual/religious components, would arm clinicians with the knowledge of which of their patients would likely prefer IMCP prior to their first encounter with that patient.

Study Overview

This study aims to identify which demographic, disease-related, psychological and spiritual/religious variables predict oncological patients' preference for IMCP. Specifically, the study will examine the relationship between treatment preference for IMCP and each of the following variables: age, education, type of cancer, depression, anxiety, hopelessness, desire for hastened death, spirituality, and religiosity. Furthermore, this study aims to analyze whether matching patients to their preferred treatment arm impacts both engagement with the treatment delivered and the therapeutic working alliance between patient and clinician during the treatment. Of note, the term "match" will be used to describe patients who, in this randomized controlled trial, were randomly assigned to the treatment they had a priori expressed a preference to receive. The term "mismatch" will be used to describe patients who, in this randomized controlled trial, were randomly assigned to a treatment they had not endorsed as their preference prior to randomization. These terms are borrowed from a larger literature on alcoholism treatment research (Del Boca & Mattson, 1994) that investigates the question of matching in randomized controlled trials. These terms do not indicate that the group assignment involved actively matching patients to a particular treatment or was anything other than random.

Study aims and hypotheses.

Aim 1: To identify which demographic variables predict participants' preference for IMCP. This aim is intended to investigate which demographic variables predict study participants' preferences for IMCP compared to a relatively traditional form of psychotherapy, Individual Supportive Psychotherapy (ISP). Specifically, this aim examines whether variations in age and education are associated with preferences for IMCP compared to ISP.

Age. Studies have demonstrated that, when given the option, age plays a role in preferences for psychological treatment over psychopharmacological treatment, with younger patients preferring psychological treatment (Feeny et al., 2009; McHugh et al., 2013) compared to medication. However, there is less literature on the role of age in studies comparing different psychotherapies. There is some evidence to suggest that religion is a critical part of older adults' lives. One study (Newport, 2006) found that 72% of older adults reported that religion was "very important" and 19% of older adults reported that religion was "fairly important" to them. Although IMCP is not described as a "religious psychotherapy" during the pre-randomization procedures, it seems likely that IMCP would resonate with individuals who prioritize religion, given its emphasis on themes like creating and enhancing meaning in life in the face of adversity. Nevertheless, the question still remains whether such older individuals, who often have an interest in religion, would prefer to engage in IMCP due to its potential familiarity, or if these participants would prefer to engage in a more traditional form of therapy that may be dissimilar from treatments or experiences they are accustomed to. Indeed, some research has supported the hypothesis that individuals tend to avoid medical treatments they lack experience with (Ezra, Gotkine, Goldman, Adahan, & Ben-Hur, 2012), allowing for the possibility of the opposite effect--that patients are attracted to treatments that fall within the boundaries of their comfort zone, as would be the case for older patients and IMCP.

In addition, other research has suggested that, as age increases, remaining years of life decrease and quality rather than quantity of life becomes the priority (Sommers et al., 2008). A meaning-centered therapy approach may sound appealing to older individuals who are focused on enriching their quality of life through focusing on its meaning.

Hypothesis 1a. Study participants who are older in age will be significantly more likely to endorse IMCP compared to ISP as their preference.

Education. When given the option between psychotherapy treatments and psychopharmacological treatments, there is some evidence that higher levels of education predict preference for psychotherapy (Feeny et al., 2009). Although the role of education in predicting preferences for psychotherapy type among a range of psychotherapies is less-studied, some research indicates that patients with less education reported feeling that spending time on spiritual issues was necessary even if that meant forgoing time spent on medical issues (MacLean et al., 2003). This suggests that patients with less education may prioritize spending time on spiritual issues and, thus, may be more likely to endorse IMCP as their preference given the presumed affiliation it has with spirituality. Further support for this hypothesis is found in a study on preferences in patients with depression (Raue et al., 2011).

Hypothesis 1b. Study participants with fewer years of education will be significantly more likely to endorse IMCP compared to ISP as their preference.

Aim 2: To identify whether cancer type predicts participants' preference for IMCP. The overall purpose of this aim is to investigate whether cancer type predicts study participants' preferences for IMCP compared to a relatively traditional form of psychotherapy, ISP.

Cancer type. The participants in this randomized controlled trial share in common that they all have stage 4, metastatic cancer. Despite uniformity in illness stage, these patients differ in their diagnoses, as patients with various types of solid tumor cancers, such as cancer of the lung, pancreas, colon/rectal area, breast, and prostate are included in the trial. Although there are several benefits to including patients with various types of cancers within a single study, some researchers have pointed to the problems inherent in mixing "apples and oranges" (Spiegel, 2004, p. 133). Indeed, studies suggest that patients with different types of cancers confront different physical issues (Spiegel, 2004). For example, in addition to symptoms they share in common with patients with other types of cancers, patients with breast cancer reported struggling with body disfigurement (Ceradini & Levine, 2008). Patients with lung cancer identified coughing and dyspnea as common concerns (Akin, Can, Aydiner, Ozdilli, & Durner, 2010; Shin et al., 2015). Patients with cancers of the gastrointestinal tract experience abdominal swelling and pain, nausea, vomiting, constipation, diarrhea, and anorexia (American Cancer Society, 2016).

Similar to the way patients with different types of cancers face different physical challenges, some researchers (Moussas, Papadopoulou, Christodoulaki, & Karkanias, 2012) argue that cancer type may also determine the nature of the psychological challenges a patient faces. For example, patients with breast cancer report issues such as feeling unattractive, dating urgency, apprehension about sexual relationships and functioning, negative body image, loss of femininity, and low self-esteem (Park et al., 2015; Shaw, Sherman, & Fitness, 2015). Patients with lung cancer identified health-related stigma as a concern (Chambers et al., 2015; Scott, Crane, Lafontaine, Seale, & Currow, 2015) whereas patients with cancers of the gastrointestinal tract reported issues related to their dietary habits (Moussas et al., 2012). Given that patients with different types of cancers experience different psychological issues, some have suggested that, rather than utilize a one-size-fits-all approach to treatment, it is more effective to design psychological treatments that target disease-specific psychological issues (Moussas et al., 2012). With a myriad of psychological interventions available, it is logical that different treatments may appeal to patients with different cancer diagnoses; however, it is not evident or intuitive which treatments patients with various cancer types would prefer when the options are not tailored to a cancer symptom profile, as is the case with IMCP versus ISP.

Prior research offers one possible explanation for predicting preference from the type of cancer diagnosis. Studies suggest that as severity of illness increases, there is an increase in the proportion of patients who desire to engage in spiritual discussion, from 33% of patients during a physician office visit, to 40% during hospitalization, to 70% in a death and dying setting (MacLean et al., 2003). Although patients in this trial all had severe diagnoses compared to patients with early-stage disease, there are still varying levels of severity within a metastatic population, which may be captured by the mortality rate or ferocity associated with specific cancer types. According to the American Cancer Society, in 2016, it was estimated that lung cancer lead to 158,080 deaths, following next by colorectal cancer, which was responsible for markedly fewer deaths--49,190 (American Cancer Society, 2016). It is well established that lung cancer is the leading cause of cancer death in the United States (American Cancer Society, 2017). In addition to lung cancer, in the case of pancreatic cancer, 80% of patients are diagnosed with advanced stage disease. Coupled with the fact that there are limited treatment possibilities, a 95% mortality rate within one year of diagnosis and a 4% survival rate (Sherman, McGuire, Free, & Cheon, 2014), evidence indicates that pancreatic cancer also falls on the more extreme end of the severity spectrum. By contrast, breast cancer survivors comprise the largest proportion of cancer survivors (Raque-Bogdan et al., 2015) and, in one study, patients with breast cancer reported lower rates of mixed anxiety and depression symptoms compared to patients with other solid tumors including both lung and pancreatic cancers (Brintzenhofe-Szoc, Levin, Li, Kissane, & Zabora, 2009). Thus, those with cancers with higher mortality rates or a more aggressive nature, as is the case with lung and pancreatic cancers, may be more likely to prefer IMCP due to the presumed spiritual tone of the therapy compared to patients with a greater chance of survival, as is the case with breast cancer for example.

Hypothesis 2a. Patients with lung cancer or pancreatic cancer will be more likely than patients with other types of cancer to prefer IMCP compared to ISP.

Aim 3: To identify which psychological variables predict participants' preference for IMCP. The third aim of the present study is to investigate which psychological variables predict study participants' preferences for IMCP compared to a relatively traditional form of psychotherapy, ISP. Specifically, this aim examines whether variations in depression, anxiety, hopelessness, and desire for hastened death are associated with preferences for IMCP compared to ISP.

Depression. Depression is common in the context of cancer, with approximately one-fourth of cancer patients becoming depressed (National Cancer Institute, 2016). There is mixed evidence regarding the role of depression in predicting patient preferences for psychological treatments in randomized controlled trials. Given the treatable nature of depression (American Psychological Association, 2016), these patients often have or have had some degree of involvement with psychotherapeutic interventions, whether alone or in combination with antidepressant medication (Karyotaki et al., 2016). On the one hand, as discussed in connection with hypothesis 1a, individuals may be more likely to prefer treatments they are familiar with (Ezra et al., 2012). This would lead one to believe that patients with depression may be more likely to prefer ISP, as it is more similar to a traditional, evidence-based psychotherapy they are likely to be accustomed to. Indeed, in one study of patients with depression, participants with a history of psychotherapy treatment were more likely to prefer medication, psychotherapy, or a combination of the two, as opposed to a spiritual treatment. The authors offered one possible explanation for this preference--that the greater the experience an individual has with a treatment for depression, the more comfort they have in engaging in an identical or similar treatment (Raue et al., 2009). On the other hand, some research suggests that there is a rooted sentiment that innovative treatments are superior to existing alternative treatments (Chalmers et al., 1997), indicating that patients with depression who are familiar with psychotherapy may prefer IMCP, as its unfamiliar nature holds the potential for untapped promise.

Unrelated to the evidence for preferring a treatment that represents familiarity or innovation, there is additional research to suggest that patients with depression may prefer IMCP. According to one study, ethnically diverse participants seeking management for depression preferred a mental health treatment that would allow them active participation and involvement (Patel & Bakken, 2010). As discussed in relation to hypothesis 1b, given that IMCP is described as a treatment that involves participation outside of the therapy setting in the form of reading a book and completing homework, patients with depression may be more inclined to endorse IMCP as their preference. In another study, patients with depression often reported engaging in religious practices, which may indicate that these individuals would prefer IMCP given its religious undertones (Barrera et al., 2012). Therefore, although the evidence is mixed in some aspects, there seems to be a stronger rationale for patients with depression leaning toward IMCP.

Hypothesis 3a. Study participants with higher levels of depression will be significantly more likely to endorse IMCP compared to ISP as their preference.

Anxiety. As is the case with depression, anxiety is also common in cancer patients. Over a five year period, over 10,000 cancer patients at two major cancer centers were screened using the Psychosocial Screen for Cancer questionnaire (Linden, Vodermaier, Mackenzie, & Greig, 2012). The study found that 19% of patients exhibited clinical levels of anxiety and an additional 23%

of patients exhibited subclinical symptoms of anxiety. Given the treatable nature of anxiety, there is reason to believe that many patients with anxiety have in the past or at the time of study enrollment engaged in psychotherapy. Thus, a similar rationale as that outlined in hypothesis 3a in relation to patients with depression may apply--patients with high levels of anxiety may prefer ISP because it represents familiar territory or, just the opposite, IMCP because it is innovative and holds promise as a previously untapped source of success.

Examination of additional prior literature further complicates the ability to form a clear hypothesis. According to one study surveying the treatment preferences of a community sample of older adults, 76% of participants preferred psychotherapy, compared to 13% who preferred medication and 11%, combined treatment. Furthermore, when asked to identify preferences for type of psychotherapy, the majority endorsed either cognitive behavioral therapy (29%) or supportive therapy (27%), whereas religious-based therapies and mindfulness were only preferred by 5% and 4%, respectively (Mohlman, 2012). Unfortunately, findings from this study are questionable, as participants were asked to imagine they suffered from anxiety and did not actually have anxiety. Nevertheless, these results offer insight into the ways in which individuals conceptualize the experience of anxiety and the preferences of patients with anxiety. Further compounding this issue is evidence to the contrary. In other studies, individuals with anxiety expressed a preference for actively participating in the mental health decision making process (Patel & Bakken, 2010) and involvement in religious practices (Barrera et al., 2012), both of which characterize IMCP.

Although the prior literature is inconsistent, there is a strong rationale for hypothesizing that, in relation to their impact on predicting preferences for a type of psychotherapy, anxiety may work in much the same way as depression, given that the two are highly comorbid disorders. In one study assessing anxiety disorders in patients with late-life depression, the authors found a comorbidity rate of 39% (van der Veen, van Zelst, Schoevers, Comijs, & Voshaar, 2015). In another large-scale study of over 1700 patients, the Netherlands Study of Depression and Anxiety, the authors found even higher rates of comorbidity; of the participants diagnosed with a depressive disorder, 67% had a current comorbid anxiety disorder and 75% had a lifetime comorbid anxiety disorder. Of those with an anxiety disorder at the time of study enrollment, 63% had a depressive disorder and 81% had a depressive disorder at some point in their lifetime (Lamers et al., 2011). In cancer specifically, the comorbidity rates are much lower but still substantial. One study (Boyes, Girgis, D'Este, & Zucca, 2011) of over 1,000 cancer patients with various types of malignancies reported a comorbidity rate for anxiety and depression of 9%, whereas a study (Sharpley, Bitsika, & Christie, 2010) of nearly 500 patients with prostate cancer estimated a comorbidity rate of 16%. Although anxiety and depression are distinct mental disorders, they often co-occur and, when left with uncertainty from an inconsistent literature, it is more sensible to group them together than separately.

Hypothesis 3b. Study participants with higher levels of anxiety will be significantly more likely to endorse IMCP compared to ISP as their preference.

Hopelessness. An increasing amount of research attention has been devoted to hopelessness in recent years, given its relationship with many other critical variables, particularly in oncology samples. Studies have demonstrated that hopelessness is correlated with depression, worry, anxiety, and maladaptive coping (Grassi et al., 2010; Yildirim, Sertoz, Uyar, Fadiloglu, & Uslu, 2009), and some research has identified hopelessness as one of the strongest predictors of desire for hastened death (Shim & Hahm, 2011). Thus, a deeper understanding of the ways in which hopelessness relates to patient preferences is a warranted endeavor, as matching hopeless patients with their preferred type of psychotherapy may confer such benefits as improving their clinical outcomes.

There is some research to suggest that patients with high level of hopelessness may prefer IMCP compared to ISP. In one study assessing the presence of demoralization, which includes hopelessness, in 55 terminally-ill cancer patients, the authors found that those with higher levels of demoralization desired to discuss survival (Vehling et al., 2015), a component that study participants might believe to be more prominent in the IMCP arm. In another study of 110 radiation oncology patients, higher levels of hopelessness were related to a preference for engaging in spiritual practices (Guz, Gursel, & Ozbek, 2012).

Hypothesis 3c. Study participants with higher levels of hopelessness will be significantly more likely to endorse IMCP compared to ISP as their preference.

Desire for hastened death. Desire for hastened death plays a critical role in the formulation of the IMCP intervention. In a description of his work, Breitbart traces the history of his research to an initial interest in physician assisted suicide, which broadened into an interest to understand desire for hastened death and despair at the end of life in terminally-ill patients. Breitbart was introduced to the work of Viktor Frankl and noted that Frankl's work about meaning seemed relevant to patients with cancer he had treated clinically, and particularly those with high levels of a desire for hastened death (Breitbart, 2003). Merely stating that IMCP was designed for patients high in a desire for hastened death does not necessarily indicate that these patients prefer IMCP. However, given a lack of empirical evidence to the contrary, one may rationalize that a treatment designed to appeal to patients high in desire for hastened death would be the option they would prefer.

Hypothesis 3d. Study participants with higher levels of desire for hastened death will be significantly more likely to endorse IMCP compared to ISP as their preference.

Aim 4: To identify which spirituality-related variables predict participants' preference for IMCP. The fourth aim of the present study is to investigate which spirituality-related variables predict study participants' preferences for IMCP compared to a relatively traditional form of psychotherapy, ISP. Specifically, this aim examines whether variations in spirituality and religiosity are associated with preferences for IMCP compared to ISP.

Spirituality. In the context of comparing one psychological treatment over another, one would be remiss in not examining the role of patients' spirituality in predicting preferences for a seemingly spiritually-oriented type of psychotherapy. Overall, studies show a general inclination on the part of patients to discuss spiritual concerns. Research demonstrates that physically ill patients desire to engage in spiritual discussions and yearn to have their spiritual concerns addressed (MacLean et al., 2003). In one study, 83% of patients surveyed from a convenience sample desired that their physicians inquire about their spiritual beliefs, particularly in the context of discussing a life-threatening illness (McCord et al., 2004). This rate is comparable to that found in a cancer sample; according to one study of 425 patients with various types of cancers, 83% of respondents identified spiritual issues as a matter worthy to be addressed (Sherman et al., 2007).

This evidence is noteworthy but merely tells us that most patients enrolled in these studies desire to address spiritual issues, suggesting an overall preference for meaning-centered therapy. This research falls short of describing the characteristics of the participants and the emphasis that they each place on spirituality, as well as how that emphasis relates to preference for spiritual discussions. This research omits the information necessary to predict whether patients high in spirituality would be more likely to prefer a meaning-centered therapy because it is more of the same, or whether patients low in spirituality would be more likely to prefer a meaning-centered therapy as a means to increase their deficit in spirituality.

Hypothesis 4a. There will be a significant difference among patients with varying levels of spirituality in preferences for IMCP compared to ISP.

Religiosity. Although they are often used interchangeably or combined into a single variable (Miller & Thoresen, 2003), there is a distinction between spirituality and religiosity. Spirituality may be described as a personal journey to understand ultimate questions about the meaning of life and relationships with that which transcends life (Koenig, King, & Carson, 2012). Some authors conceptualize spirituality as a broad concept that encompasses meaninglessness, hope, helplessness, loneliness, and religiosity (Morita et al., 2004). By contrast, religiosity may be described as a structured system of beliefs, practices, rituals, and symbols aimed at enabling a relationship with that which transcends life (Koenig et al., 2012). Thus, it is entirely possible for an individual to be high in spirituality while low in religiosity.

There is a body of evidence in support of the hypothesis that patients high in religiosity may be more likely to indicate a preference for IMCP given its religious undertones. One study suggests that highly religious patients may benefit from engaging in a psychotherapy that breaks from tradition. This research demonstrated that religious patients with generalized anxiety disorder experienced a greater decrease in anxious symptoms when they received a religious therapy compared to a supportive therapy (Azhar, Varma, & Dharap, 1994). Outcome, however, differs from preference. According to one survey of physician and patient preferences for the role of religion in medical care, patients with greater worship attendance, and therefore likely higher in religiosity, were more likely to agree that time spent on spiritual issues was warranted, even if that meant less time to discuss medical concerns (MacLean et al., 2003). In another study, patients higher in religious faith, as well as those who more often used religious based coping, indicated a preference for incorporating religiosity into their psychotherapy regimen (Barrera et al., 2012). Despite the fact that these studies are few in number, there is a dearth of opposing evidence, allowing a clear hypothesis to emerge.

Hypothesis 4b. Study participants with higher levels of religiosity will be significantly more likely to endorse IMCP compared to ISP as their preference.

Aim 5: To investigate whether matching patients to their preferred treatment arm impacts their engagement with their assigned treatment in a randomized controlled trial and their therapeutic alliance mid-way through the course of treatment.

Engagement with Treatment. Elsewhere in this dissertation, in the context of the potential benefits of understanding patient preferences, evidence supporting the idea that matching patients to their preferred treatment arm may increase their engagement with the intervention was discussed. One related study, however, provides some evidence to the contrary. In an attrition-related manuscript using data from a randomized controlled trial comparing the group version of IMCP to the group version of ISP, members of the Breitbart research team hypothesized that participants matched to their preferred treatment would be less likely to drop out of the study compared to those who were mismatched to their preferred treatment. The authors' hypothesis was unsupported, as the match between preference for treatment and assigned treatment did not predict attrition in this study (Applebaum et al., 2012). Although there is mixed evidence in the larger literature for the role of match and its relationship to attrition, one rationale is that greater weight should be given to the group IMCP trial given its similarities to the IMCP study trial from which the data for these analyses are drawn. It is important to note, however, that in the current study, the focus is on engagement with treatment or the number of therapy sessions attended, whereas in the attrition paper using group IMCP data, the focus was on attrition from the randomized controlled trial. Although engagement in treatment overlaps with engagement in the study, they are two different constructs.

Hypothesis 5a. There will be no significant difference in number of therapy sessions attended between patients who are randomly assigned to their preferred treatment arm and patients who are randomly assigned to the therapy arm they did not endorse as their preference.

Therapeutic Alliance. Working alliance may be understood as a collaboration between the therapist and the patient (Greenson, 1965). There has been considerable attention paid to investigating whether patients ethnically matched to their therapists, compared to those with different ethnicities as their therapists, report a more positive working alliance. In one study of 67 patients with mental health illnesses, those in the ethnically matched group indicated higher scores on the working alliance measure compared to those in the ethnically non-matched group (Chao, Steffen, & Heiby, 2012). In another study of 171 Asian American participants, those racially matched to their therapist reported greater feelings of experiential similarity to their therapist, which was positively related to therapist credibility rating (Meyer, Zane, & Cho, 2011). Nevertheless, ethnic matching is distinct from preference matching. It is important to consider that the feelings study participants have toward the therapy type may transfer to their feelings toward the therapist, as well. The relatively small literature on preference matching is consistent with the findings from ethnic matching research; one study demonstrated that in a sample of patients with Major Depressive Disorder, mismatch between preferred and randomized treatment was related to a weaker working alliance during the treatment (Kwan et al., 2010).

Hypothesis 5b. Patients who are randomly assigned to their preferred treatment arm will report a more positive working alliance with their therapist than patients who are randomly assigned to the therapy arm they did not endorse as their preference.

Method

The data for these analyses are part of a larger R01 study funded by the National Cancer Institute to Dr. William Breitbart, the Chair of the Department of Psychiatry and Behavioral Sciences at Memorial Sloan Kettering Cancer Center. The larger study, similar to a former study using the group version of each therapy (Breitbart, 2003), aims to compare the efficacy of IMCP, a standardized ISP and Enhanced Usual Care (EUC) in improving meaning, spiritual well-being, and overall quality of life, and reducing psychological distress including depression, anxiety, hopelessness, and desire for hastened death, in a sample of advanced cancer patients. EUC, the third treatment arm, was not discussed previously, as the focus of the analyses for this dissertation is to compare two types of psychotherapy interventions rather than a targeted referrals and resources arm, as is the case with EUC.

For the larger study, participant recruitment commenced in March 2011 at Memorial Sloan Kettering Cancer Center in New York City, New York, a major cancer center in an urban location. Research study assistants, including this author, screen the electronic medical records of patients seen at the outpatient cancer clinics of the hospital to determine study eligibility. Criteria for inclusion are: (1) age 21 years or older; (2) score of 4 or higher on the Distress Thermometer (Roth et al., 1998); (3) Karnofsky Performance Rating Scale (KPRS; Coscarelli-Schag, Heinrich, & Ganz, 1984; Karnofsky & Buchenal, 1949) score of 60 or greater; (4) ability to understand and communicate in English; and (5) a confirmed diagnosis of stage 4 disease for breast, prostate, or colon cancers, solid tumor malignancies at other sites that are metastatic, locally recurrent ovarian cancer, or confirmation from the treating physician and documentation in the research medical record of advanced disease. Patients were excluded if they have a severe psychiatric disturbance as determined by the research study assistant or physical limitations sufficient to preclude participation.

Patients meeting all inclusion criteria were approached for possible study participation either in person during their chemotherapy treatments, via phone or via informational mailing (see Appendix A for sample consenting script). Patients refusing participation cited reasons such as limited time, lack of interest, or geographic or scheduling barriers. Others agreed to participate, and complete a battery of pre-randomization measures, which included the question related to preference for treatment, as well as the consent form (see Appendix B for written informed consent document). Shortly thereafter, patients were randomized to one of the three treatment arms: IMCP, ISP or EUC. Those receiving either of the two psychotherapy treatments received seven 1-hour one-to-one clinician and patient sessions. Although the majority of the sessions took place at the Memorial Sloan Kettering Counseling Center, in some circumstances such as illness or inclement weather, sessions were conducted via phone. The seven sessions must have occurred within 14 weeks, but could be done weekly, bi-weekly, or three weeks on, one week off. All therapists on the study were trained facilitators (all of whom had at least a Master’s degree in a mental health discipline; e.g., psychology, psychiatry or social work). Study sessions were audio recorded for review during supervision, as well as for treatment integrity verification. Participants were offered a $20 travel reimbursement when they arrived at the counseling center for each session. Patients in either of the two therapy arms completed a battery of questionnaires at four different time points throughout the study: as previously mentioned, at pre-randomization/consent (T0; see Appendix C), immediately before the first therapy session/baseline (T1; see Appendix D), immediately before the fourth therapy session/midpoint (T2), directly following the seventh/last session/post-intervention (T3) and 8-12 weeks following completion of the T3/follow-up (T4).

Although the characteristics of IMCP were previously discussed, it is critical to elaborate on the elements of ISP in this trial. The ISP arm of the study is designed to provide support and focuses on topics such as how to communicate with your physician and family, how to obtain information about treatment, and how to handle side effects of treatment (Breitbart, 2003). The essential components of ISP are integrated into this treatment: reassurance, explanation, guidance, suggestion, encouragement, affecting changes in the patient’s environment, and permission for catharsis (Block, 1996). The ISP process emphasizes Rogerian person-centered concepts: genuineness, unconditional positive regard, and empathic understanding. This therapy emphasizes maintaining focus on cancer, supporting patients in the here and now, fostering expression of emotion, discussion of difficult topics, and creating a sense of being understood (Payne et al., 1997).

By contrast, patients randomized to the third treatment arm, EUC, were provided with a supply of targeted referrals and resources specifically designed to meet their needs as they reported them during the pre-randomization measures. These resources included a book, the *Human Side of Cancer*, written and signed by Dr. Jimmie Holland, the Chair in Psychiatric Oncology at Memorial Sloan Kettering Cancer Center and the psychiatrist widely recognized as the founder of the field of psycho-oncology, as well as pamphlets from Gilda’s club and American Cancer Society, and contact information for specific referrals in the local area. Patients randomly assigned to the EUC arm of the study completed a nearly identical battery of questionnaires (omitting inappropriate questionnaires such as those dealing with therapeutic alliance) at similar time points to those in the therapy arms.

For the larger study, research assistants kept a list of eligible, potential patients to approach and, in March of 2011, began formal recruitment of patients on this list, as well as incoming patients. Over the course of approximately 5 years (from March 2011 to March 2016), 6,410 individuals were screened and deemed eligible for participation in this study as per protocol requirements. Of the 6,410 patients who were eligible, 6,089 either refused participation, citing reasons such as geographic barriers, limited time, and lack of interest, or were subsequently deemed ineligible due to reasons such as language barriers and cognitive impairment. In the end, 321 patients consented to the study, which represents about 5% of the screened and eligible sample. The last patient to consent did so on 3/30/2016, exactly 5 years after the first patient consented. The last patient who completed the study returned the final questionnaire on 8/13/2016.

This investigator (Allison Marziliano) joined the Breitbart research team in July of 2011 as a Research Study Assistant and, until August of 2016, has been a part of study recruitment, constructing the study database, entering and cleaning study data, and assisting with collection of questionnaires and creating reports. In contrast to the larger study, which is primarily focused on evaluating the impact of IMCP on clinical outcome measures, the focus of this study is on the role of critical variables in relation to patient preferences and the impact of the match between preference for treatment and assignment to treatment on therapeutic engagement and alliance. Thus, the analyses in this study use the pre-randomization and baseline data, as well as one measure (The Working Alliance Inventory-Standard Form; WAI-SF) collected mid-way through the course of therapy.

Measures

The battery of questionnaires for the larger study incorporated both standardized and non-standardized measures, which will be noted briefly in this section prior to a more in-depth discussion of the specific measures utilized for the purposes of this proposal. For the larger study, standardized data collection instruments were: the Distress Thermometer (Roth et al., 1998), Karnofsky Patient Performance Rating (KPRS; Coscarelli-Schag et al., 1984; Karnofsky & Buchenal, 1949), Life Attitude Profile-Revised (LAP-R; Reker, 1992), Life Orientation Test-Revised (LOT-R; Scheier & Carver, 1985), McGill Quality of Life Questionnaire (MQoL; Cohen et al., 1995), Memorial Symptom Assessment Scale- Short Form (MSAS-SF; Portenoy et al., 1994), the Duke-UNC Functional Social Support Questionnaire (FSSQ; Broadhead et al., 1988), and the Prognostic Awareness Patient Rating (Lichtenthal et al., 2009; Prigerson, 1992; Ray et al., 2006). Non-standardized measures were: Prognostic Awareness Clinician Rating, Health Information Preferences, Psychiatric Information, Post-intervention Questionnaire, Unfinished Business Questionnaire, and an optional weekly session rating for the IMCP-centered arm only.

For the purposes of this study focused on predicting patient preferences and the impact of matching patients to their preference on engagement with treatment and therapeutic alliance, the following measures were analyzed:

The Pre-randomization Preference Questionnaire (PRP). This 4-item face valid questionnaire was developed by the investigators to assess patients' preferences for aspects of the three types of psychotherapy interventions. This measure consists of three questions soliciting to what degree (not at all, slightly, somewhat, quite a bit, very much) participants prefer the program to focus on providing support, talking about feelings about cancer, and finding a sense of meaning and purpose in life despite having cancer. The fourth and final question requires that participants indicate their preference if they were able to choose a preference, with the options IMCP, ISP, EUC, and no preference. In accordance with a similar published manuscript on a study of meaning-centered group psychotherapy (Applebaum et al., 2012), the single categorical question in this measure will be used to determine preference. As a manipulation check, we conducted independent sample *t*-tests to determine if there were significant differences between patients who responded to the categorical question with a preference for meaning and those who responded with a preference for support on two of the continuous measures ("how much would you prefer this program focus on providing support?" and "how much would you prefer this program focus on finding a sense of meaning and purpose in life despite having cancer?"). Participants were informed that their responses were solely for analytical purposes and would not influence their therapy assignment.

The Sociodemographic Questionnaire. This non-standard measure consists of 14 questions assessing variables including age, gender, race, ethnicity, marital status, number and ages of children, years of education, employment status, occupation, concern over financial status, religion, and to what degree participants consider themselves religious or spiritual individuals or attend religious services.

The Health Status Interview. This non-standard measure consists of three health-related questions regarding type of cancer, treatment history and status, and concurrent medical conditions. Specifically, patients indicated their primary site of cancer, selecting from a list of diagnoses such as breast, colorectal, esophageal, kidney, liver, melanoma, pancreatic, prostate, ovarian and uterine.

The Hospital Anxiety and Depression Scale (HADS). The HADS (Zigmond & Snaith, 1983) is a 14-item self-rated questionnaire, which has been well-tested as a measure of overall psychological distress in cancer populations, with Depression and Anxiety subscales of seven items each. It is considered particularly useful because of the absence of somatic items that often confound the determination of psychiatric problems among medically ill individuals. It has demonstrated strong test-retest reliability in samples of elderly patients (Spinhoven et al., 1997) and HIV positive patients (Savard et al., 1998).

The Functional Assessment of Chronic Illness Therapy- Spiritual Well-Being Scale (FACIT-Sp). The FACIT-Sp is a brief self-report measure designed to assess the nature and extent of an individual's spiritual well-being (Brady et al., 1999). This measure generates two subscales: one corresponding to faith and a second assessing meaning and peace. The measure has been demonstrated to have strong internal reliability for both the total score as well as each subscale (coefficient alpha = .87 for the total scale, .88 for the faith factor, and .81 for the meaning factor). Furthermore, strong support for the external validity of this measure has been demonstrated in several large samples of cancer and AIDs patients, including patients with advanced and terminal illness (Brady et al., 1999; Breitbart et al., 2001; Nelson, Rosenfeld, Breitbart, & Galietta, 2002).

The Intrinsic/Extrinsic Religiosity Scale (IE-12). The IE-12 is a 12-item self-report measure that assesses intrinsic and extrinsic religiosity (Maltby, 1999). This measure has adequate internal consistency reliability (coefficient alpha range = .66 to .75) and has been increasingly used with elderly and medically ill populations (e.g., Nelson et al., 2002).

The Hopelessness Assessment in Illness Questionnaire (HAI). The HAI (Rosenfeld et al., 2011) is an 8-item measure that is targeted for hope and hopelessness in advanced illness.

The HAI has demonstrated a high degree of internal consistency (coefficient alpha above .80) and construct validity (such as a correlation of .74 with clinical ratings of hopelessness).

The Schedule of Attitudes toward Hastened Death (SAHD). This 20-item questionnaire is a self-report measure of interest in hastened death (Rosenfeld et al., 1999). This measure has been administered to more than 300 patients with terminal cancer and HIV/AIDs and has demonstrated high levels of reliability (alpha coefficient = .88 and median item-total correlation = .43). The SAHD has demonstrated concurrent validity, correlating .88 with a clinician-rated desire for death rating scale (Chochinov et al., 1995) and more modestly (*r* = .47 to .65) with measures of depression and overall psychological distress.

Working Alliance Inventory-Short Form (WAI-SF; see Appendix E). The original WAI is a 36-item instrument designed to measure variables affecting the degree of counseling success based on Bordin's (1979) conceptualization of the therapeutic alliance, independent of the counselor's theoretical orientation (Horvath et al., 1989). There are three subscales of the WAI (tasks, goals and bonds) as well as a composite score. Cronbach's alpha of the WAI composite score is .93 (Horvath et al., 1986). This study utilized a shortened version of the WAI, which consists of a 12-item total with four items in each of the three subscales. Validity has been demonstrated for the WAI-SF based on a similar factor structure with the original 36 item WAI. Cronbach's alpha for the WAI-SF range from .83 to .98 (Busseri & Tyler, 2003).

Two other variables not part of the questionnaire battery but necessary for the analyses of this dissertation were recorded. Patients' attendance at each of the therapy sessions, which was the measure of engagement in therapy, was recorded as was the treatment each patient was randomized.

Analytic Strategy

Data was analyzed using Statistical Package for the Social Sciences (SPSS), Version 21. As a manipulation check, responses to the categorical preference question on the Pre-randomization Preference Questionnaire were compared across the various consenting professionals conducting the consent and pre-randomization procedures. Additionally, we compared basic demographics of consenters and non-consenters to identify whether those who consent to study participation differ from those who refuse participation in fundamental ways. We also compared drop-out rates by study arm at each time point. Prior to running analyses, all variables were subjected to a vigorous cleaning process. This consisted of examining the mean, standard deviation, range, minimum, and maximum for all continuous variables using the descriptive statistics function in SPSS. Any unusual or out-of- range values were noted and subject to further inspection. In addition, the frequency function in SPSS was used to screen all data for missing entries and incompleteness. In addition, the data were also screened for outliers, defined as values that fall more than three standard deviations away from the mean, as well as skewness and kurtosis.

Aim 1. To investigate Aim 1, which focuses on identifying which, if any, demographic variables predicted patients' preference for IMCP, logistic regression was used. Two variables (age and education) were included as predictors in the logistic regression in order to determine the unique relationship of each variable with the categorical outcome: preference for IMCP or preference for ISP.

Aim 2. To investigate Aim 2, which focuses on identifying whether cancer type predicts patients' preference for IMCP, logistic regression was used. One variable, type of cancer, was included as a predictor in the logistic regression in order to determine this predictor's relationship with the categorical outcome: preference for IMCP or preference for ISP.

Aim 3. To investigate Aim 3, which focuses on identifying which, if any, psychological variables predict patients' preference for IMCP, logistic regression was used. Four variables (depression, anxiety, hopelessness, and desire for hastened death) were included as predictors in the logistic regression in order to determine the unique relationship of each variable with the categorical outcome: preference for IMCP or preference for ISP.

Aim 4. To investigate Aim 4, which focuses on identifying which, if any, spirituality-related variables predict patients' preference for IMCP, logistic regression was used. Two variables (spirituality and religiosity) were included as predictors in the logistic regression in order to determine the unique relationship of each variable with the categorical outcome: preference for IMCP or preference for ISP.

The statistical software program, G*power (Faul, Erdfelder, Lang, & Buchner, 2007), was used to estimate the sample size necessary to conduct each of the four logistic regression analyses with 80% power and an odds ratio of 1.5, which is a small effect size. The program yielded a required sample size of 231 participants.

Aim 5. To investigate Aim 5, which focuses on identifying whether assigning patients to their preferred treatment arm impacts engagement with treatment and the quality of the working alliance with the therapist, two 2 treatment preference (IMCP vs. ISP) x 2 treatment assignment (IMCP vs. ISP) ANOVAs were used.

The statistical software program, G*power (Faul et al., 2007), was used to estimate the sample size necessary to conduct each of the two 2x2 ANOVA analyses with 80% power and a medium effect size of .25. The program yielded a required sample size of 128 participants.

Results

Preliminary Analyses

Comparing consenters and non-consenters. An independent sample *t*-test and chi-square analyses were utilized to assess whether patients who consented were significantly different than patients who refused study participation on the variables of age, gender and cancer type. Given the large number of patients who declined participation (approximately 6,000 patients over the course of 5 years), a random sample of 254 decliners was selected to represent the group of decliners, and was compared to the 254 consenters included in these analyses. An independent sample *t*-test was conducted to assess whether there was a significant difference in age between patients who consented to participate in this study and those who declined participation in the study. Results indicated that consenters (M = 57.65, SD = 10.94) were significantly younger than non-consenters (M = 61.24, SD = 12.02); $t(507) = -3.52$, $p = .00$. Chi square analyses were utilized to compare consenters and non-consenters in terms of gender and cancer type. Consenters were more likely to be female, X^2 (1, N = 507) = 23.21, $p = .00$, and have breast cancer as opposed to other cancers than non-consenters, X^2 (1, N = 507) = 84.69, $p = .00$.

Study attrition. High rates of attrition are common in studies of patients with terminal illnesses (Applebaum et al., 2012), as patients often become too sick or die before completing study assessments. In this study, 109 participants were randomized to IMCP and 108 to ISP. Ninety-three patients in the IMCP treatment arm completed the baseline questionnaire, compared to 85 in the ISP arm. Eighty patients in the IMCP arm completed the mid-point questionnaire, compared to 73 patients in the ISP arm. Seventy-eight patients in the IMCP arm completed the post-intervention questionnaire, compared to 70 patients in the ISP arm. Sixty-four percent (n = 70) of the patients assigned to IMCP completed the final follow-up assessment and 49% (n = 53) of the patients assigned to ISP completed the final assessment. Chi square analyses were utilized to identify significant differences between the number of participants completing questionnaires at each of the four time points (baseline, mid-point, post-intervention, and final follow-up) by psychotherapy study arm (IMCP or ISP). A significant relationship was found between completion of the baseline questionnaire and study arm, X^2 (1, *N* = 178) = 3.88, *p* = .05. However, there were no significant differences by study arm and completion of the mid-point questionnaire, X^2 (1, *N* = 153) = .02, *p* = .92, the post-intervention questionnaire, X^2 (1, *N* = 148) = .02, *p* = .90, and the final follow-up questionnaire, X^2 (1, *N* = 123) = 1.55, *p* = .22.

Tests of Main Hypotheses

Descriptive statistics. The study sample (*N* = 254) was mostly female (*n* = 185; 72.8%), White (*n* = 205; 80.7%), non-Hispanic (*n* = 228; 89.8%), married (*n* = 157; 61.8%), and just more than half identified as either Catholic (*n* = 82; 32.3%) or Jewish (*n* = 68; 26.8%; see Table 1 for exact gender, race, ethnicity, marital status and religion breakdown). The average age of this sample is 57.65 (*SD* = 10.94), ranging from 25 to 85 years old. The average years of education completed by this sample was 16.59 (*SD* = 2.57), with a range of 10 to 25 years of education completed.

The Pre-randomization Preference Questionnaire. When asked to select their preference for IMCP, ISP, or EUC, patients are reminded that their assignment to a treatment is completely random and their response to this question will have no effect on their assignment. In response to this question, 141 (43.9%) of patients endorsed IMCP, 113 (35.2%) patients endorsed ISP, 13 (4.0%) patients endorsed EUC, and 54 (16.8%) patients endorsed "no preference." Thus, for the purposes of these analyses, we used a sample of 254 patients who endorsed either IMCP or ISP.

In order to verify the validity of the single, categorical preference question ("we would like to know if you were able to choose, which program would you prefer?") in ascertaining participants' preference, two follow-up questions were analyzed. Participants who endorsed ISP as their preference scored higher on the first question (*M* = 3.11, *SD* = .91), "How much would you prefer the program to focus on providing support?", than did participants who endorsed IMCP as their preference to the categorical question (*M* = 2.76, *SD* = 1.11), *t*(251) = -2.74, *p* = .01. Similarly, participants who endorsed IMCP as their preference scored higher on the second question (*M* = 3.24, *SD* = .94), "How much would you prefer the program to focus on finding a sense of meaning and purpose in life despite having cancer?", than did participants who endorsed ISP as their preference to the categorical question (*M* = 2.14, *SD* = 1.19), *t*(207) = 7.99, *p* = .00.

Given that 11 different consenting professionals over the course of five years verbally administered the pre-randomization preference questionnaire to study consenters, a logistic regression was conducted to predict preference for IMCP using consenting professional as the predictor. A test of the full model against a constant model was not statistically significant, indicating that the individual consenting professional did not reliably distinguish between preference for IMCP and preference for ISP, chi square = 10.45, *p* = .41 with df = 10. Nagelkerke's R^2 of .06 indicated a very weak relationship between prediction and grouping. Prediction success overall was 57.9% (80.1% for preference for IMCP and 30.1% for preference for ISP). The Wald criterion demonstrated that consenting professional did not make a significant contribution to prediction (*p* = .75).

Aim 1 results: demographic predictors. See Table 2 for the descriptive statistics for the main study variables. A logistic regression analysis was conducted to predict preference for IMCP using age and years of education as predictors. A test of the full model against a constant only model was statistically significant, indicating that the predictors as a set reliably distinguished between preference for IMCP and preference for ISP, chi square = 12.60, *p* = .01 with df = 2. *Nagelkerke's* R^2 of .07 indicated a very weak relationship between prediction and grouping. Prediction success overall was 61.4% (80.9% for preference for IMCP and 37.2% for preference for ISP). The Wald criterion demonstrated that only years of education made a significant contribution to prediction (*p* = .01). Age was not a significant predictor. Exp(B) value indicated that when education is raised by one unit, the odds ratio is .84 times as large and therefore participants are only .84 times more likely to prefer ISP. Thus, higher education predicted a preference for IMCP.

Aim 2 results: cancer type. A logistic regression analysis was conducted to predict preference for IMCP using cancer type as a predictor. *Nagelkerke's* R^2 of .01 indicated a very weak relationship between prediction and grouping. Prediction success overall was 55.5% (100% for preference for IMCP and 0% for preference for ISP). The Wald criterion demonstrated that cancer type did not make a significant contribution to prediction (*p* = .08). Thus, whether participants were diagnosed with lung or pancreatic cancer versus another type of cancer did not relate to their preference for one type of therapy vs. the other.

Aim 3 results: psychological variables. A logistic regression analysis was conducted to predict preference for IMCP using depression, anxiety, hopelessness and desire for hastened death as predictors. A test of the full model against a constant only model was not statistically significant, indicating that the predictors as a set did not reliably distinguish between preference for IMCP and preference for ISP, chi square = 5.70, *p* = .23 with df = 4. *Nagelkerke's* R^2 of .04 indicated a very weak relationship between prediction and grouping. Prediction success overall was 54.2% (78.4% for preference for IMCP and 24.4% for preference for ISP). Based on the

Wald criterion, none of the predictors made a significant contribution to prediction. Thus, none of the psychological variables predicted preference for type of therapy.

Aim 4 results: spirituality/religiosity variables. A logistic regression analysis was conducted to predict preference for IMCP using levels of spirituality and religiosity as predictors. A test of the full model against a constant only model was not statistically significant, indicating that the predictors as a set did not reliably distinguish between preference for IMCP and preference for ISP, chi square = 2.03, *p* = .37 with df = 2. Nagelkerke's R^2 of .02 indicated a very weak relationship between prediction and grouping. Prediction success overall was 51% (81.3% for preference for IMCP and 14.6% for preference for ISP). Based on the Wald criterion, neither of the predictors made a significant contribution to prediction. Thus, levels of spirituality or religiously were not related to preference for type of therapy.

Aim 5 results. A 2 treatment preference (IMCP vs. ISP) x 2 treatment assignment (IMCP vs. ISP) ANOVA was used to identify whether assigning patients to their preferred treatment arm impacts their engagement with the therapy, as measured by number of sessions attended. The interaction between treatment preference and treatment assignment was not significant, *F*(1,163) = 1.60, *p* = .21. The main effect for treatment preference yielded an F ratio of *F*(1,163) = 1.09, *p* = .30, indicating no significant difference in number of sessions attended between those who preferred IMCP (*M* = 4.91, *SD* = .30) and those who preferred ISP (*M* = 5.39, *SD* = .35). The main effect for treatment assignment yielded an F ratio of *F*(1,163) = .82, *p* = .37, indicating no significant difference in number of sessions attended between those who were assigned to IMCP (*M* = 5.36, *SD* = .32) and those who were assigned to ISP (*M* = 4.94, *SD* = .33).

A 2 treatment preference (IMCP vs. ISP) x 2 treatment assignment (IMCP vs. ISP) ANOVA was used to identify whether assigning patients to their preferred treatment arm impacts the quality of the working alliance with the therapist. The interaction between treatment preference and treatment assignment was significant, *F*(1,116) = 9.41, *p* = .01. Simple effects analyses demonstrated that patients who preferred IMCP and were assigned to IMCP scored the highest on the Working Alliance Inventory (*M* = 72.62, *SD* = 1.89), and patients who preferred IMCP and were assigned to ISP scored the lowest on the Working Alliance Inventory (*M* = 63.68, *SD* = 2.17), and this difference was statistically significant *F*(1,116) = 9.67, *p* = .01. By contrast, in patients who preferred ISP, there was no significant difference in the mean on the Working Alliance Inventory between those assigned to IMCP (*M* = 67.21, *SD* = 2.17) and those assigned to ISP (*M* = 71.22, *SD* = 2.21), *F*(1,116) = 1.68, *p* = .20. See Figure 1 for a plot of the significant crossover interaction. The main effect for treatment preference yielded an F ratio of *F*(1,116) = .26, *p* = .62, indicating no significant difference on the Working Alliance Inventory between those who preferred IMCP (*M* = 68.15, *SD* = 1.44) and those who preferred ISP (*M* = 69.22, *SD* = 1.55). The main effect for treatment assignment yielded an *F* ratio of *F*(1,116) = 1.37, *p* = .25, indicating no significant difference on the Working Alliance Inventory between those who were assigned to IMCP (*M* = 69.92, *SD* = 1.44) and those who were assigned to ISP (*M* = 67.45, *SD* = 1.55).

Discussion

This study aimed to identify whether certain demographic, disease-related, psychological, and spiritual/religious variables predict patients' preference for IMCP, a novel psychotherapy based on creating meaning in life, compared to ISP, a more traditional supportive psychotherapy, in a sample of individuals with advanced cancer. We hypothesized that patients characterized by older age, less education, lung or pancreatic cancer, and higher levels of depression, anxiety, hopelessness, desire for hastened death and religiosity would prefer IMCP compared to ISP.

Although we believed it would significantly predict preference for IMCP, an a priori directional hypothesis for spirituality could not be formulated due to inconsistencies in the current related literature. Our results demonstrated that, contrary to our hypothesis, level of education significantly predicted a preference for IMCP, such that patients with *higher* levels of education were more likely to endorse IMCP as their preference. All other predictors were not significant.

Furthermore, the study aimed to determine whether matching patients to their preferred psychotherapy impacted their engagement with the treatment, as measured by the number of therapy sessions attended, and their therapeutic alliance with their therapist, as measured by the WAI-SF. We hypothesized that matching to treatment preference would not impact engagement with the treatment, but would have a positive impact on the therapeutic alliance measured mid-way through the course of therapy. Our results supported both of these hypotheses. First, there was no significant difference in engagement with therapy between those who matched to their preferred treatment and those who mismatched to their preferred treatment. Second, patients who matched to their preferred treatment, compared to those who mismatched, had stronger working alliances with their therapists mid-way through the course of therapy. This was especially the case for those patients who preferred IMCP, as the difference in alliance was significant between those who preferred and received IMCP (matched) and those who preferred IMCP but received ISP (mismatched). Although those who preferred ISP and received ISP (matched) also had a stronger alliance than those who preferred ISP but received IMCP (mismatched), the difference was not significant.

Higher Levels of Education Predict a Preference for IMCP

We hypothesized that patients with lower levels of education would be more likely to prefer IMCP compared to ISP. The impetus for this hypothesis was two prior studies in which patients with less education felt it was appropriate to spend time discussing spiritual issues with their doctor even if it meant sacrificing time spent discussing medical issues (MacLean et al., 2003; Raue et al., 2011). The findings from our study indicate the opposite- that patients with higher levels of education are more likely to prefer IMCP compared to ISP. These prior studies, although the closest we have to inform our hypotheses, clearly differ from our study in two critical ways. First, these prior studies included patients from primary care clinics, compared to our study based on patients with advanced cancer. Second, these prior studies reference discussing spiritual matters, which is related to a meaning therapy but not exactly the same.

In the context of our study results, there are plausible reasons why individuals with higher levels of education may prefer IMCP. The presentation of IMCP to patients involves mention of didactics, manuals and structure, all of which are familiar and may be appealing to individuals who have been in school for a longer amount of time. On the other hand, patients with lower levels of education may prefer ISP because the practicalities of IMCP (homework, manuals, etc.) may sound intimidating. In a similar vein, the description of IMCP to patients pre-randomization colors it as a sophisticated-sounding treatment based on abstract philosophies. This description may attract individuals with higher education levels, who are accustomed to “thinking and learning”, compared to individuals who chose work over school, and are accustomed to “doing”.

Match/Mismatch as Significant Predictor of Therapeutic Alliance

In areas other than cancer research, there is a large and growing literature on the construct of therapeutic alliance and its critical role in predicting patients’ positive clinical and psychological outcomes. In a study of 84 patients with Major Depressive Disorder, improvement of the patient-rated therapeutic alliance predicted a significant reduction in depressive symptoms at a follow-up session (Falkenstrom, Ekeblad, & Holmqvist, 2016). In other research on 118 individuals with Binge Eating Disorder receiving 20 sessions of emotionally focused therapy, authors found that consistent growth in alliance was related to reduced binge eating behavior 6 months post-treatment (Tasca, Compare, Zarbo, & Brugnera, 2016). Similar positive findings occurred in a study of adults in treatment for Bulimia Nervosa, whereby increases in patients' therapeutic alliance ratings predicted greater reductions in bulimic behavior (Accurso et al., 2015), and health anxiety, whereby stronger working alliances significantly predicted health anxiety improvement (Hedman, Andersson, Lekander, & Liotsson, 2015). Thus, there is a great deal of evidence supporting the role of therapeutic alliance in leading to positive outcomes in patients with psychiatric illness.

Within cancer research, the focus on therapeutic alliance encompasses not only research on the relationship the patient has with his or her therapist, but also on the relationship between the patient with cancer and his or her oncologist or medical team. In a multi-site, prospective, longitudinal study of 396 patients with advanced cancer, the Coping with Cancer Study, patient-physician therapeutic alliance at enrollment was positively correlated with patient's quality of life at end of life (Zhang, Nilsson, & Prigerson, 2012). Similarly, in other research with advanced cancer patients, the authors found that a strong therapeutic alliance between patients and the medical staff was positively correlated with treatment adherence, improved health outcomes, and emotional acceptance of a terminal illness (Bar-sela, Mitnik, & Lulav-Grinwald, 2016). In a study of 93 young adult patients with incurable, recurrent or metastatic cancer, those reporting a strong therapeutic alliance with their oncologist were at a reduced risk of suicidal ideation after controlling for confounding variables such as cancer diagnosis, performance status, depression, and social support (Trevino et al., 2014). Therefore, within the context of cancer care, strong therapeutic alliance between the oncology medical team members and the patient predicts positive psychological outcomes.

Similar findings are present in studies examining clinical outcome as a result of the relationship between the patient with cancer and his or her therapist, rather than oncologist. As stated in Sturgiss, Sargent, Haesler, Rieger, and Douglas (2016), “therapeutic alliance is a well-recognized predictor of patient outcomes within psychological therapy” (p. 376). In a study of survivors of hematopoietic stem cell transplantation receiving cognitive-behavioral therapy for post-traumatic stress disorder, higher therapeutic alliance predicted decreased: depressive symptomatology, overall stress, symptoms of re-experiencing and symptoms of avoidance (Applebaum et al., 2012). In another study of 225 women with gynecological cancer receiving a coping and communication intervention or client-centered supportive therapy, early patient-rated working alliance predicted improved session progress and a decrease in depressive symptoms post-sessions (Manne et al., 2016). Furthermore, evidence suggests that a strong therapeutic alliance, either between patient and therapist or between patient and oncologist, may have benefits that extend beyond the patients’ outcomes to positively affect caregivers, as well (Higgins & Prigerson, 2013; Manne, Kashy, Siegel, & Heckman, 2016; Trevino, Maciejewski, Epstein, & Prigerson, 2015). Therefore, results of this research, which demonstrates that matching patients to their preferred treatment, particularly in the case of IMCP, positively impacts therapeutic alliance, shed light on this critical relationship variable, which has been demonstrated as a predictor of positive clinical and psychological outcomes.

The preceding paragraphs demonstrate the importance of gaining a better understanding of therapeutic alliance, given its important role in outcome. However, matching to treatment preference, the focus of this manuscript, is merely one predictor of therapeutic alliance. There are a host of other predictors that appear in the literature, both at the patient and therapist level, that have an impact on the formation of a strong therapeutic alliance.

At the patient level, there is evidence that certain demographic variables are predictive of a stronger therapeutic alliance. For example, in a study of 107 male perpetrators of intimate partner violence, Caucasian patients reported a significant improvement in therapeutic alliance with time, whereas individuals in a racial/ethnic minority group did not indicate a consistent pattern of improvement in therapeutic alliance (Walling, Suvak, Howard, Taft, & Murphy, 2012). In addition to race/ethnicity, this study demonstrated that being married, older age, and higher income predicted a stronger therapeutic alliance (Taft, Muphy, Musser, & Remington, 2004).

Beyond demographic variables, there is evidence that certain patient traits or characteristics are related to a stronger therapeutic alliance. In a study of patients engaging in treatment for drug misuse, patients utilizing better coping strategies were more likely to report a strong alliance with their therapist (Meier, Donmall, Barrowclough, McElduff, & Heller, 2005). Other research has pointed to the following patient-level and patient-rated factors as predictors of strong therapeutic alliance: motivation and readiness to change, expectation of treatment success, greater need for treatment, greater problem recognition, greater social support, and secure attachment style (Folke, Daniel, Poulsen, & Lunn, 2016; Garner, Godley, & Funk, 2008; Meier et al., 2005; Ruchlewska, Kamperman, van der Gagg, Wierdsma, & Mulder, 2016; Stiles-Shields et al., 2016; Taft et al., 2004). On the other hand, other research has indicated patient personality pathology as leading to weaker therapeutic alliance (Olesek et al., 2016; Taft et al., 2004; Verheul, van den Brink, & Hartgers, 1998).

To compliment the research on patient-level factors, there is an emerging body of literature on therapist-level factors, as rated by the patient, and their impact on therapeutic alliance. In a study of 48 patients with psychotic disorder, perceived therapist genuineness was indicated as the most significant predictor of therapeutic alliance. Other therapist-level factors that lead to a stronger working alliance in this sample included therapist competence, empathy, and acceptance (Jung, Wiesjahn, Rief, & Lincoln, 2015). In other studies, therapist age and experience positively predicted alliance, while therapist education level negatively predicted alliance (Connors et al., 2000; Meier et al., 2005).

Rather than focusing solely on patient-level variables or therapist-level variables, some research has been devoted to the interaction between the two. Whereas the focus on this study was on matching patients to their preferred treatment and its impact on therapeutic alliance, there are also ways to match patients with therapists, including by language, and race or ethnicity. In a study assessing Spanish-speaking patients attending primary care clinics, evidence from qualitative interviews indicated that patients preferred bilingual providers rather than interpreters, as language matching was associated with more privacy, trust and accuracy in communication (Villalobos et al., 2016). Matching patients and therapists on ethnicity has also been demonstrated to improve working alliance in a sample of patients with mental illness (Chao et al., 2012).

The findings from this study contribute to the larger literature on predictors of working alliance previously described, as well as the more focused literature on matching patients to their preferred treatments in RCTs and matching as a predictor of alliance. Our study results that matching to treatment preference, compared to mis-matching to treatment preference, results in a more positive alliance is consistent with this more focused literature. In one study of 75 patients with Major Depressive Disorder enrolled in an RCT comparing supportive expressive therapy, sertraline, and pill placebo, patients who preferred and matched to psychotherapy had stronger alliances with their therapists, than patients who preferred psychotherapy but were assigned to one of the other treatment arms (Iacoviello et al., 2007). In another study of patients with depression, mismatch between preferred and received treatment was related to a weaker working alliance (Kwan et al., 2010). Thus, the evidence indicates matching to treatment preference as an important indicator of therapeutic alliance.

It is true that our study results indicate matching to treatment preference as a significant predictor of alliance; however, the findings disproportionately favor preference for IMCP, compared to preference for ISP, as being more critical in affecting alliance. That is, there is a significantly stronger alliance for those patients who prefer IMCP and receive it (match) than there is for those patients who prefer IMCP and receive ISP (mismatch). By contrast, although patients who prefer ISP and receive ISP (match) indicate a stronger alliance than those patients who prefer ISP and receive IMCP (mismatch), the difference is not significant. Thus, one might argue that matching in general is important and this is true; however, moving one step further, matching is particularly important in this study when the patients' preference is IMCP.

There are several reasons that a preference for IMCP, but not ISP, may lead matched patients to report the strongest alliances and mismatched patients to report the weakest alliances. First, IMCP is a novel technique not offered elsewhere, either clinically or in the context of research, at the time this RCT was ongoing. Thus, patients with a strong preference for IMCP may feel disappointed when receiving ISP as their treatment because they have "missed out" on the only opportunity to engage in IMCP, and this pre-conditioned disappointment may bleed into their relationship with the therapist. Next, ISP is less restrictive than IMCP in regard to content discussed during sessions. Therefore, if an individual prefers ISP and is mismatched to receive IMCP, the therapist will focus on meaning topics but there is room for that focus to shift if the patient desires. By contrast, if a patient prefers IMCP because he or she only wants to discuss meaning in life, that patient may be met with frustration when their ISP therapist steers the conversation away from meaning topics for the sake of maintaining treatment fidelity in the context of the study. Of note, the measure of therapeutic alliance used for this study, the WAI-SF, ranges from 7-84. Even the lowest scoring group (those who preferred IMCP and received ISP) had a mean score of 63, indicating that although alliance was stronger for some patients, it was strong for the sample overall.

Unexamined Predictors

There were several other variables included in this dataset (gender, race/ethnicity, time since diagnosis and occupational status) that were potentially interesting predictors of patients' preference for IMCP. However, in the context of little to no prior related research on these predictors, or inadequate measurement of the construct, directional a priori hypotheses could not be formulated for these variables. Therefore, they were not included in our various sets of predictors but because they are often variables that are of interest, are discussed briefly in the subsequent paragraphs.

Gender. There is consistent evidence that females are more likely to choose psychological treatments compared to medication (McHugh et al., 2013). However, the evidence is much less consistent with regard to the role of gender in selecting among different psychotherapies. Some research (Patel & Bakken, 2010) suggests that female gender, compared to male gender, is associated with preference for greater involvement in mental health decision making. Given that IMCP is described as a therapy in which the patient will actively engage both in discussion with the therapist as well as in readings between therapy sessions, one might hypothesize that women, more so than men, would prefer this relatively involved psychotherapy.

Other research (Raue et al., 2009), which indicates that males are more likely to prefer medication, psychotherapy, or a combination of the two over spiritual treatment, represents a different approach to the role of gender in preference for IMCP. Similar to how IMCP is not described as a religious treatment, it is not described as a spiritual treatment during the pre-randomization procedures; however, one could assume that many patients are attuned to the spiritual tone of a therapy focused on enhancing meaning in life.

On the other hand, other research has demonstrated that it is male patients who may be more likely to prefer IMCP when it is offered as an alternative to ISP, which may represent a less desirable option from the male viewpoint. One study reported that men preferred groups with an emphasis on education rather than emotional support (Berglund, Bolund, Gustafsson, & Sjoden, 1997; Krizek, Roberts, Ragan, Ferrara, & Lord, 1999), as is characteristic of traditional Supportive Psychotherapy groups. This view is confirmed by a survey of prostate cancer patients conducted by the Breitbart research team; the authors found that 80% of participants were more interested in attending a group focused on meaning as opposed to a traditional psychotherapy group focused on feelings and emotions (Breitbart, 2003). Thus, although there is evidence that gender does play a role in preferences for psychotherapy treatments, there is less consistent support for whether men or women are the group more likely to prefer a meaning-centered therapy. As a result, gender was not included as a predictor of preference for IMCP.

Race/ethnicity. There is evidence that ethnicity does play a role in preference for type of psychotherapy; however, as was the case with gender, it is unclear which ethnic background or backgrounds would lead to a preference for IMCP. One study reported that being Hispanic was related to a more passive rather than active role in health care decision making (Patel & Bakken, 2010). One possible explanation offered by this research team was that Hispanics' preference for a relatively passive role may be the result of their low health literacy or self-efficacy. As such, when offered a treatment with a book, readings, and weekly homework, as is the case with IMCP, Hispanic patients may be more likely to choose the alternative out of fear or angst of engaging in what they may envision to be a complicated therapeutic treatment.

In yet another study examining the preferences of patients with depression (Raue et al., 2009), authors found that Hispanic patients more often preferred medication, psychotherapy or a combination of the two treatments compared to spiritual treatments. This study lends support to the concept that Hispanic patients may endorse a preference for ISP compared to IMCP. On the other hand, other research (Barrera et al., 2012) suggests that older adults with minority backgrounds report a greater level of participation in religious activities, indicating that Hispanic individuals may be more inclined to prefer IMCP given its religious undertones. This competing evidence makes it difficult to conclude anything beyond that there is likely to be a difference between Hispanics and non-Hispanics with regard to their preferences for IMCP compared to ISP.

In addition to Hispanic and non-Hispanic ethnicity, some studies offer insight into the difference between Caucasian and African American participants' preferences for treatment. From the outset, African American patients, compared to Caucasian patients, may be less inclined to engage in psychotherapy treatment, as one study reported that African American women, compared to Caucasian women, more often pointed to shame and stigma as deterrents to participating in support groups (Simonton & Sherman, 2000). However, both IMCP and ISP are psychotherapy groups and could be conceived of as equally stigmatizing; therefore, this prior research provides little insight to inform this research question. When given the option between these two treatments, there is some evidence that African American patients, compared to

Caucasian patients, are more likely to desire to incorporate spiritual components into their treatment (Raue et al., 2009; Simonton & Sherman, 2000), indicating that African American women, compared to Caucasian women, would be more likely to prefer IMCP. Nevertheless, race/ethnicity were not examined as predictors for preference for IMCP given the inconsistent nature of this literature.

Time since diagnosis. There is evidence to suggest that time since diagnosis may impact patient preferences for mode of information delivery. One study of 237 patients with prostate cancer found that there were differences in preference for mode of information delivery based on how long the patients were post-diagnosis. The authors compared a sample of prostate patients who were on average 4 months post-diagnosis to a sample of prostate patients who were on average 1.9 years post-diagnosis. The researchers concluded that patients with more recent diagnoses preferred their information to be presented via doctor's interview, informational booklet or guided tour, compared to those who were longer post-diagnosis and preferred their information via individual training and educational videos (Sharpley & Christie, 2009). In another study, an anonymous survey of 253 patients with breast cancer demonstrated that there were differences in preference for the format of information delivery between patients diagnosed less than one month before study enrollment and patients diagnosed two years before study enrollment (Sharpley, Bitsika, & Christie, 2011). The authors offer the explanation that differences in these preferences may be due to elevated levels of anxiety and depression at times when patients are closer to diagnosis, and suggest that format of information delivery should be altered based on patients' location along the post-diagnosis trajectory (Sharpley et al., 2011). Such findings indicate the potential for differences in preference for not only format of information delivery but also type of psychological intervention based on how long patients are post-diagnosis. Unfortunately, given this limited literature, a directional hypothesis for time since diagnosis as a predictor of preference for IMCP would be ill-informed.

Occupational status. There is minimal evidence on the role of occupational status in predicting patient preferences for psychotherapy treatments. One available study (MacLean et al., 2003) surveying patients in primary care clinics found that patients with less income were more likely to agree that spiritual issues were worthy of time during appointments, even if spending time on spiritual issues left less time to discuss medical issues. Such a preference for discussion of spiritual issues on the part of low income individuals signals that there is some evidence that those with low income may be more likely to prefer IMCP. In the absence of a specific question on income bracket in this study, the Hollingshead Index (Hollingshead, 1975) was utilized to capture patients' occupational status, as occupational status and income are often correlated. However, in reviewing this measure, it became clear that the categories were not compatible with or sufficiently descriptive of our sample. For example, 37 participants (11.5%) indicated that they were unemployed, potentially placing homemakers, students, retirees, and unemployed individuals all in the same category despite that their income level may be quite different. For this reason, we omitted income/occupational status as a predictor of preference for IMCP.

Limitations

There are several limitations inherent in studying patient preferences for treatment. First, it is difficult to define and identify true preference. Particularly in medical settings, patients form decisions in the broader context of emotional, social, and familial influences. Some might argue that these preferences do not represent the individuals' true preferences because of the tumultuous context within which the preference was formed. Others might argue just the opposite--that many studies from which we base our hypotheses are invalid because the participants indicate their preferences in the context of hypothetical situations free of duress (Montori et al., 2013). Indeed, a systematic review (King et al., 2005) of the impact of patient and physician preferences for interventions in randomized controlled trials concluded that patients' immediate responses may not stand up to deeper reflection in the minutes, hours and days after a preference is indicated. There is literature to support the findings that preferences may be influenced by framing effects, verbal descriptions of risks and benefits, and the preference or characteristics of the individual presenting the possible treatments (Edwards & Elwyn, 2001; Jenkins, Fallowfield, & Saul, 2001). Other research focused on affective forecasting undermines the notion that individuals are accurate in predicting their feelings (Kermer et al., 2006; Wilson & Gilbert, 2005). It is unclear, due to a lack of research on the topic, how anticipated preferences for treatment, actual treatment and post-treatment preferences relate to each other (King et al., 2005) and which, if any, represents a true preference.

Furthermore, methods for soliciting patient preferences are often weak, lacking rigorous, standardized elicitation and instead relying on a single question in the consent procedures. Authors have suggested that documenting patient preferences should be held to the same high standards as other aspects of randomized controlled trials (King et al., 2005). Examples of more rigorous research designs of this nature include the preference randomized controlled trial paradigm, in which patients with preferences are given their preferred treatment while those without preferences are randomized (Brewin & Bradley, 1989), as well as offering participants another treatment if they do not want the treatment they received via random assignment (Janevic et al., 2003). Although these alternative designs provide more accurate research on patient preferences, they are difficult to undertake, given such barriers as the fact that they require large sample sizes and are thus more time-consuming and expensive (Howard & Thornicroft, 2006).

Other limitations inherent in studying patient preferences include that study findings are only generalizable to a subset of individuals--those who agree to be randomized. Randomized controlled trials omit those who are so strongly opposed to randomization and subsequently undergoing a treatment they do not prefer, which is a sample with potentially different characteristics from those who consent to randomization (George & Robinson, 2010; Howard & Thornicroft, 2006). On the other hand, in this study regarding patient preferences, these study participants represent a group willing to be randomized and, therefore, potentially more liberal and flexible with their treatment preferences. We compared basic demographics of consenters and non-consenters in this study and found that consenters were more likely to be younger women who were diagnosed with breast cancer, and there are numerous other ways in which these two groups have the potential to differ. In some studies, individuals may offer their preference for a treatment or decision after having already engaged in said treatment or decision. In this context, patients' preference may be muddied by hindsight bias, cognitive dissonance or regret, as the patients navigate through the repercussions of their decisions (Montori et al., 2013).

In regard to limitations of the larger study, it should be noted that the study participants comprise a fairly homogenous group of highly educated, employed, and Caucasian patients, thereby restricting generalizability to other populations. In regard to the specific limitations present in these analyses, it is critical to discuss our use of the term "spiritual" as somewhat synonymous with "meaning-centered" treatment. In this proposal, many of our hypotheses reflect research based on preferences for spiritual discussions or information, which we indicate as a preference for IMCP, thereby conflating the two terms. Although the intuitive connection between the two terms was discussed briefly elsewhere in this proposal without reference to the literature, some authors, in fact, do conceptualize spirituality as a broad concept that encompasses meaningfulness (Morita et al., 2004). Regardless of the degree to which the two terms are related, whether based on personal opinion or empirical evidence, the use of literature on spirituality to form hypotheses about a meaning-centered therapy was necessitated by the lack of literature on preferences for IMCP, which forms part of the impetus for conducting this study.

Another limitation in conducting these sub-analyses is our inability to examine social support and its relationship to preferences for IMCP. One might hypothesize that patients with strong support systems would shy away from the ISP arm, thereby gravitating toward the IMCP arm out of process of elimination. However, this does not tell us whether patients high in social support prefer IMCP because it is their genuine preference, or if these individuals prefer IMCP as the more attractive psychotherapy alternative to ISP, which they may not feel they need. In light of no prior literature with which to form a hypothesis, this question remains unexamined. Lastly, although individuals verbally reported that they desired to drop from the trial due to reasons such as disease progression, mismatch to preferred treatment, or logistical barriers, formal systematic documentation of the reasons individuals discontinue their participation in the trial was not recorded.

Conclusion

The findings from this study have broader implications for research on psychotherapy beyond IMCP. A consistent profile of an individual who prefers a specific type of psychotherapy may not exist. Beyond that, these results serve as a reminder that novel, sophisticated-sounding psychotherapy treatments may be intimidating to patients with low levels of education. When developing interventions, or the pre-randomization descriptions of such, it is critical to keep descriptions of innovative treatments clear and at a reading level commensurate to the average education level of the study sample. Furthermore, although matching patients to their preferred treatment does not appear to impact their engagement with the treatment in terms of the number of sessions attended, it does impact their alliance with the therapist, which in turn, may impact their clinical outcomes. Given that the comparison of IMCP and ISP in this study is analogous to comparing a novel treatment to an established standard of care in other RCTs, it is important to note that alliance, and outcome, may suffer when patients do not receive their preferred treatment, particularly when their preference is a novel therapy they cannot engage in elsewhere.

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Table 1

Descriptive Statistics

Category	Frequency	Percent
Gender		
Male	69	27.2%
Female	185	72.8%
Race		
Caucasian	205	80.7%
African Am.	24	9.4%
Asian	11	4.3%
Other	14	5.5%
Ethnicity		
Non-Hispanic	228	89.8%
Hispanic	24	9.4%
Unknown	2	.8%
Marital Status		
Single	37	14.6%
Married	157	61.8%
Widowed	18	7.1%
Separated	8	3.1%
Divorced	29	11.4%
Cohabitating	5	2.0%
Religion		

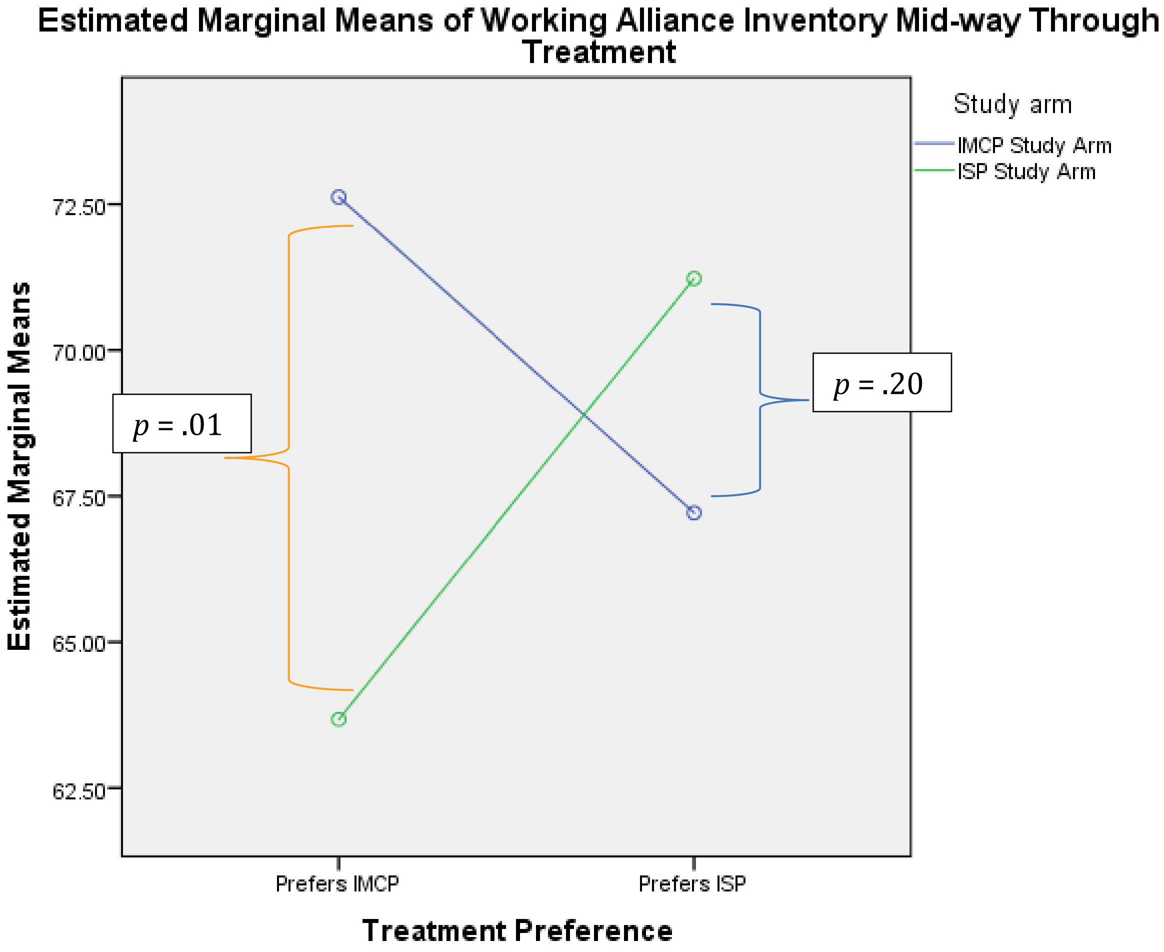
Catholic	82	32.3%
Protestant	14	5.5%
Jewish	68	26.8%
Baptist	3	1.2%
Muslim	3	1.2%
Other	44	17.3%
None	40	15.7%

Table 2

Descriptive Statistics of Main Variables

Variable	Mean (*SD*)	Range	Frequency
Age	57.65 (*10.94*)	25-82	-
Education	16.59 (*2.57*)	10-25	-
Cancer Type	-	-	*n* = 31 (lung) *n* = 36 (pancreatic)
Depression	5.78 (*3.50*)	0-18	-
Anxiety	8.54 (*4.05*)	1-19	-
Hopelessness	5.07 (*3.45*)	0-16	-
Desire for Hast. Death	2.62 (*2.92*)	0-18	-
Spirituality	28.38 (*9.49*)	1-48	-
Religiosity	29.89 (*3.61*)	24-36	-
No. of Sessions Atten.	5.75 (*2.86*)	0-7	-
Therapeutic Alliance	68.96 (*11.87*)	27-84	-

Figure 1. Significant crossover interaction and pairwise comparisons indicating a significant difference between patients who prefer and receive IMCP and those who prefer IMCP and receive ISP



Appendix A.

Consenting Script

My name is Allison and I work at the Counseling Center. We were just going around speaking with patients about a free study we have. Would you be interested in hearing about it?

If yes….

As I said, I work at the Counseling Center. Some patients are not aware that Memorial Sloan Kettering has a Counseling Center so we like to make sure patients know that these services do exist for patients and family members. We are located right across the street through the Atrium.

The project I work on is a research study which is why we are able to offer it for free. How it works is you sign up to participate and then you are randomly assigned to one of three treatment arms- so what that means is that there are three possibilities and I will tell you about all three of them but you are not able to choose which of the three you receive. Do you understand that?

The first treatment arm is called individual Meaning-Centered Psychotherapy. This is 7 1-hour long sessions where you would be 1 on 1 with the same therapist throughout all 7 sessions. They take place at the counseling center. You can do the sessions every week, every other week, three weeks on and one week off- whatever you prefer as long as they are done within 14 weeks. The content of the therapy is meaning centered therapy so it is structured and based on a book by Viktor Frankl called Man's search for meaning. The therapy has to do with creating, enhancing and sustaining meaning in life in the face of adversity and there is a specific theme that your discussion is centered around each week.

The second treatment arm is called individual Supportive Psychotherapy which is identical to the first arm in terms of the logistics, so it is 7 1-hour long sessions where you would be 1 on 1 with the same therapist throughout all 7 sessions. They take place at the counseling center. You can do the sessions every week, every other week, three weeks on and one week off- whatever you prefer as long as they are done within 14 weeks. What is different here is the content of this therapy. Whereas meaning centered therapy was more structured, this supportive therapy is more general support, closer to what you would think traditional therapy to be. You talk about whatever you need to, such as family or friends. It is not as structured.

Finally, the third treatment arm is very different from the other two. This arm is called Enhanced Usual Care and is referrals and resources. If you were to receive this arm, the research assistants like myself would come to your chemotherapy, take down a list of areas that may be causing you distress and put together a list of referrals and resources specifically designed to meet your needs. It would also include pamphlets and a book written and signed by the head of our department, Dr. Jimmie Holland.

Again, these are the three possibilities, but you are not able to choose which of the three you would receive.

I will also mention every time you come to the counseling center for a session, you would receive a $20 travel reimbursement. And because it is research, we ask you to complete some questionnaires for us on 4 different occasions. They each take about 25 minutes.

Does this sound like something that might be interesting to you?

Appendix B.

INFORMED CONSENT FOR CLINICAL RESEARCH

A Randomized Controlled Trial of Individual Psychosocial Interventions for Cancer Patients

Participant Informed Consent

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

A member of the study staff will explain the research study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your family and friends.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

Why is this study being done?

The aim of this study is to compare the benefits of three types of individual treatment programs for cancer patients: Meaning-Centered counseling, Supportive counseling, and Enhanced Usual Care. Many cancer patients use counseling or other resources to help with the emotional burden of their illnesses. Counseling often helps them cope with cancer by giving them a place to express their feelings. “Meaning-Centered” counseling aims to teach you how to maintain or even increase a sense of meaning and purpose in their lives, despite cancer. “Supportive” counseling is intended to help you cope with cancer by giving you a place to express your feelings and get support. Enhanced Usual Care is intended to offer you referrals and resources that are matched to your individual needs in addition to the care you are already receiving at MSKCC.

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

How was I selected to be in this study?

You have been selected to be in this study because you have non-localized and/or recurrent cancer.

How many people will take part in the study?

A total of 414 people will take part in this study at Memorial Sloan-Kettering Cancer Center. In this study, one third will receive Meaning-Centered counseling, one third will receive Supportive counseling, and one third will receive Enhanced Usual Care.

What will happen if I take part in this research study?

Before you begin the study …

Before you begin the study we will conduct a screening interview to determine if you are eligible for this study.

This screening interview will take about 20-30 minutes.

We will ask you about your background (e.g. age, ethnicity, education and marital status), medical history, and your physical and emotional well-being, We will also ask you about which treatment you would prefer.

After you complete the questionnaires if you are eligible for participation, you will be assigned to one of the three treatment programs on a random basis. This means you have an equal chance of being in any of the programs.

Then we will describe the treatment programs we are studying and if you are eligible for the study, you will be asked which type of treatment program you would prefer to receive. You will then be randomly assigned to one of the three types of treatment programs. A research study assistant will call you to tell you what type of treatment you will receive and when it will start.

During the study...

If you choose to take part, then you will be asked to do the following:

If you are put into the Meaning-Centered counseling program, it will focus on how to maintain or even increase a sense of meaning and purpose in your life. Each meeting will have a discussion that deals with a specific topic such as what is meaningful to you and how has cancer changed this. In addition, written exercises will be assigned during the session or for homework and participants will also have the option of completing a larger project on their own based on these themes. You will meet with a counselor individually for seven weekly 1 hour sessions.

If you are put into the Supportive counseling program, it will focus on helping you cope with cancer by giving you a place to express your feelings and get support. During each session you will be asked to share your concerns and discuss how you are feeling about these issues. You will meet with a counselor individually for seven weekly 1 hour sessions.

All research study counselors are either MSKCC-employed mental health clinicians or non-MSKCC employed mental health clinicians contracted to work on specific research studies. We use the services of non-MSKCC mental health clinicians as study counselors so that we can best accommodate your schedule and availability to attend Meaning-Centered or Supportive counseling sessions. All clinicians, whether employed by MSKCC or hired per research study, have at minimum a Masters degree and are qualified and experienced mental health clinicians trained in the counseling program you will receive.

If you are randomized to the Enhanced Usual Care program, you will be given referrals based on your individual needs. You will also receive additional written materials with information on how to cope better when you have cancer and additional resources that may be helpful. You will complete assessments three times and based on the results will be given referrals if needed tailored to your individual needs after each time.

Therapy sessions will be audio recorded. If you choose to allow us, we may transcribe some of these recordings for academic, educational, or training purposes, and some sessions may also be video recorded. At the end of this consent, we will ask for your permission to audio and video record your sessions and to transcribe your audio recordings. Video recording of sessions and transcription of audio recordings are optional. You can choose not to allow video recording and/or transcription and still participate.

Recording the sessions will help us make sure that the interventions are being carried out as planned. Each recording will have a code number to protect your confidentiality. In addition, some sessions may take place in front of a two way mirror in order to be observed for training and supervision purposes. You may ask to stop the recording at any time or to not be observed during the intervention and such requests will not influence your participation in the study or any of your medical care.

All participants will be asked to complete a set of self-report questionnaires before they begin the treatment program and about 4, 7 and 15 weeks after they start the treatment program. The questionnaire will take about 45-60 minutes to complete. These assessments are generally completed in person. However, if necessary we can arrange for you to complete them by mail, phone, or email. If you are in the Meaning-Centered program, we will also you to fill out an optional weekly session rating after each session. This will take about 2-3 minutes, but you can choose not to complete it. With your permission, we may also contact your doctor after you begin the study for information about your medical treatment.

You will be asked questions about the following areas:

a) Questions about your physical and psychological symptoms and quality of life

b) Questions about your religious beliefs and spiritual well-being

c) Questions about your social support and stress levels

After the study…

After you have completed the above steps, there is nothing further you must do.

How long will I be in the study?

You will be asked to take part in the study for about 15-22 weeks.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest or if the study is stopped.

What side effects or risks can I expect from being in the study?

We do not expect any physical side effects or risks with this study. There is a small chance that you may become upset by the discussions or by some of the questions we will ask you. The research staff conducting the sessions is well trained mental health professionals. They will be there during the sessions and afterwards to help provide further help. If you become very upset because of taking part in this study, you will also be offered a referral for care by the MSKCC Psychiatry staff. You will be billed for these additional services.

Are there benefits to taking part in the study?

This study may or may not benefit you. By taking part in this study, you may receive 7 weeks of Meaning Centered or Supportive Counseling free of charge or be provided with referrals to specifically meet your needs. It may help reduce the emotional difficulties you may be experiencing. We hope that what we learn from the study will help other patients in the future.

Will I receive the results from the study?

You will not receive any results from this study.

Do I have to take part in this study?

The choice to take part in this study or not is yours. Make your choice based on what we have explained to you and what you have read about the study. Whether you decide to participate in this study or not, you do have the opportunity to receive counseling and support services to help you cope with the stressors of cancer illness and treatment through either the MSKCC Department of Social Work as well as through consultation with a member of the Clinical staff of the MSKCC Department of Psychiatry.

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What are the costs of taking part in this study?

It does not cost anything to be in the study. You will be responsible for transportation to and from the hospital where the interventions will take place. However, you may choose to receive a $20 travel reimbursement for travel to the therapy sessions or assessments. In addition, if you complete all four of the study assessments you will receive a $20 gift card to Barnes & Noble as a thank you for your time and participation. If you are randomized to Enhanced Usual Care you will be given referrals at no charge. However, if you choose to accept these referrals you may be billed for these services by these providers.

What happens if I am injured because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. You will be responsible for costs associated with therapy sessions you receive outside of this study.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor William Breitbart, M.D. at 646-888-0020.

Any hospital that does research on people has an institutional review board (IRB). This

board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSKCC has reviewed this study.

For a non-physician whom you may call for more information about the consent process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

Recording of Sessions:

The counseling sessions will be audio taped in order to make sure the treatment programs are all run in the same way. These audio taped sessions may be transcribed. In addition, some sessions may be video recorded. These videos and transcripts may be used for academic, educational, or training purposes. If you do not agree, your sessions will not be videotaped and/or transcribed. However, you can still participate in the study.

Please indicate you understand you will be audio recorded as part of this study.

☐ *Yes, I understand I will be audio recorded as part of this study.*

Please indicate if you agree to be video recorded.

☐ *Yes, I agree to be video recorded.*
☐ *No, I do not wish to be video recorded but still wish to participate.*

Please indicate if your audio taped sessions can be transcribed.

☐ *Yes, I agree that you can transcribe my audio taped sessions.*
☐ *No, I do not wish for my sessions to be transcribed but still wish to participate.*

Contacting Your Doctor:

With your permission, we may contact your doctor during the study for information about your medical treatment. If you do not agree to this, we will not contact your doctor for this purpose.

Please indicate if you agree to allow us to contact your doctor for information about your medical treatment.

☐ *Yes, I give you permission to contact my doctor for this purpose.*
☐ *No, I do not wish for you to contact my doctor for this purpose.*

Future Studies:

Someone may contact me in the future to ask me to take part in more research.

☐ Yes, I would like to be contacted about future studies
☐ No, I would not like to be contacted about future studies

INFORMED CONSENT FOR CLINICAL RESEARCH

A Randomized Controlled Trial of Individual Psychosocial Interventions for Cancer Patients

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (**LAR**). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision.

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand.		
☐ **YES**	☐ **NO**	☐ **N/A (Adult or Child <7)**
Consenting Professional's Signature		**Date:**
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		**Date:**
Participant/LAR Name (Print)		
LAR Relationship to Participant		

Witness Signature (If Required)

☐ **Non-English Speaking Participant Witness and/or Interpreter:** I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).

☐ **Other:** I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: ____

Signature of Witness: ____ Date: _________________

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form.

Appendix C.
Pre-Randomization Measures

Memorial Sloan-Kettering Cancer Center
IRB Protocol #

Initials:________
Date:__________
Subject ID:_____
Data Collected By:________________________________ Date:__________
(Research Staff-Full name)
Data Entered By:________________________________ Date:__________
(Research Staff-Full name)

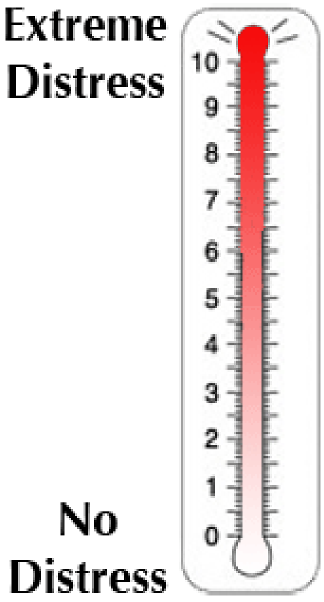
Data collected by: ____ ______
(Research Staff – Print Name) (Initial)

Please refer to the distress thermometer to **note** your current level of distress and then **check** the causes of your distress on the list below.

Please check (√) all areas that contribute to your distress:

Please note your current distress:

(0-10): ____



Practical Problems

☐ 1. Housing
☐ 2. Insurance
☐ 3. Work/School
☐ 4. Transportation
☐ 5. Child Care

Family Problems

☐ 1. Partner
☐ 2. Children

Emotional Problems

☐ 1. Worry
☐ 2. Sadness
☐ 3. Depression
☐ 4. Nervousness

Spiritual/Religious Concerns

☐ 1. Relating to God
☐ 2. Loss of faith
☐ 3. Other problems

Physical Problems

☐ 1. Pain
☐ 2. Nausea
☐ 3. Fatigue
☐ 4. Sleep
☐ 5. Getting Around
☐ 6. Bathing/dressing
☐ 7. Breathing
☐ 8. Mouth sores
☐ 9. Eating
☐ 10. Indigestion
☐ 11. Constipation/diarrhea
☐ 12. Bowel changes
☐ 13. Changes in urination
☐ 14. Fevers
☐ 15. Skin dry/itchy
☐ 16. Nose dry/congested
☐ 17. Tingling in hands/feet
☐ 18. Feeling swollen
☐ 19. Sexual Problems

KARNOFSKY PATIENT PERFORMANCE RATING (KPRS)

Able to carry on normal activity, no special care is needed	100	Normal, no complaints: no evidence of disease
	90	Able to carry on normal activity: minor signs or symptoms of disease
	80	Normal activity with effort: some signs or symptoms of disease
Unable to work: able to live at home: care for most personal needs: varying amount of assistance is needed	70	Care for self unable to carry on normal activity or do active work
	60	Requires occasional assistance but is able to care for most needs
	50	Requires considerable assistance and frequent medical care
Unable to care for self: requires equivalent of institutional or hospital care: disease may be progressing rapidly	40	Disabled: requires special care and assistance
	30	Severely disabled: hospitalization is indicated though death is not imminent
	20	Very sick: hospitalization necessary
	10	Moribund: fatal process progressing rapidly
	0	Dead
		Karnofsky Score ______

Pre-Randomization Preference Questionnaire (PRP)

Please circle the number that corresponds to your preference for the content of the individual program you will participate in based on the following questions:

1) How much would you prefer the program to focus on providing support?

0	1	2	3	4
Not at All	**Slightly**	**Somewhat**	**Quite a Bit**	**Very Much**

2) How much would you prefer the program to focus on talking about your feelings about cancer?

0	1	2	3	4
Not at All	**Slightly**	**Somewhat**	**Quite a Bit**	**Very Much**

3) How much would you prefer the program to focus on finding a sense of meaning and purpose in life despite having cancer?

0	1	2	3	4
Not at All	**Slightly**	**Somewhat**	**Quite a Bit**	**Very Much**

4) Although your assignment to either Meaning-Centered, Supportive, or the Enhanced Usual Care programs is completely random (i.e. a one third chance of any program), we would like to know if you were able to choose…

   Which program would you prefer?

   _____Meaning-Centered **_____Supportive**

   _____Enhanced Usual Care ___ No Preference

Sociodemographic Data

1. Subject #: __________

2. Age: ________

3. Sex: ____Male ____Female

4. Race:
   _____1. White or Caucasian American
   _____2. Black or African American
   _____3. Asian
   _____4. Native Hawaiian or Pacific Islander
   _____5. American Indian or Alaskan Native
   _____6. Other or Unknown (specify)____

   Ethnicity:
   _____1. Hispanic/Latino
   _____2. Not Hispanic/Latino
   _____3. Unknown

5. Current Marital Status
   _____1. Single
   _____2. Married
   _____3. Widowed
   _____4. Separated
   _____5. Divorced
   _____6. Cohabitation

6. Number of children:_______; Ages:____

7. Education: ______________________(in years)

8. What us your employment status?
   _____1. Unemployed
   _____2. Homemaker
   _____3. Part-time
   _____4. Full-time
   _____5. Student
   _____6. Disabled
   _____7. Retired
   _____8. Other____

9. Occupation:
    _____1. Unemployed
    _____2. Factory Worker/Manual Laborer
    _____3. Machine Operator
    _____4. Skilled Manual Worker, Craftsman
    _____5. Clerical and Sales Worker
    _____6. Technician. Semi-Professional, Small Business Owner
    _____7. Manager or Mid-Level Professional
    _____8. Administrator, Proprietor of Medium Business
    _____9. Higher Executive, Proprietor of Large Business, Major Professional

10. How concerned are you about you financial status?
    _____1. Not concerned at all
    _____2. No more concerned than usual
    _____3. Slightly concerned
    _____4. Very concerned
    _____5. I am so concerned that it is hard to think of anything else

11. What is your religion?
    _____1. Catholic
    _____2. Protestant
    _____3. Jewish
    _____4. Baptist
    _____5. Muslim
    _____6. Other (Specify)____
    _____7. None

12. Do you consider yourself a religious person?
    _____1. Not at all
    _____2. Somewhat
    _____3. Yes, very much

13. Do you attend religious services?
    _____1. Never
    _____2. Sometimes
    _____3. Regularly

14. Do you consider yourself a spiritual person?
    _____1. Not at all
    _____2. Somewhat
    _____3. Yes, very much

Appendix D.
T1

Memorial Sloan-Kettering Cancer Center
IRB Protocol #

Initials:________
Date:__________
Subject ID:_____
Data Collected By:________________________________ Date:___________
(Research Staff-Full name)
Data Entered By:________________________________ Date:___________
(Research Staff-Full name)

Dear Participant,

Thank you for taking the time to complete this questionnaire. Your answers to these questions will be very valuable to help us learn about the impact of our interventions and how to help patients with cancer better. Your answers to these questions will be kept confidential. Please be aware that some of the questions we ask can be sensitive in nature. We ask lots of different people these questions and they are not based on any specific information about your medical record or care. Of course, you do not have to answer any questions you do not want to. Please don’t hesitate to let us know if you have any questions or concerns.

Thank you for your time and commitment,

William Breitbart

William Breitbart, MD & Research Team

Health Status Interview

Medical Information

1. Current Cancer Diagnosis (Primary Site) - Please check only one:

___Bladder
___Brain & CNS
___Breast
___Colon/Rectum
___Esophagus
___Head & Neck
___Kidney
___Liver
___Lung & Bronchus
___Melanoma
___Pancreas
___Prostate
___Stomach
___Testis
___Thyroid
___Ovary
___Uterine Cervix
___Uterine Corpus
___Other__________________________

2. Recent Treatment History:

Chemotherapy:	___within last 3 months	____currently	___upcoming
Major Surgery:	___within last 3 months	____currently	___upcoming
Radiation:	___within last 3 months	____currently	___upcoming
Hormone Therapy:	___within last 3 months	____currently	___upcoming

3. Other medical conditions (please list):

____
____
____
____

Health Information Preferences

We recognize the next few questions may be difficult to answer but we want to have a better understanding of how patients think about their disease status.

1. Patients differ in the amount of information that they want to know about their *diagnosis and treatment*—some want to know everything, others want to know very little. What is your **preference for details of information** about your diagnosis and treatment? *Please check one.*

   ☐ I prefer not to hear a lot of details.
   ☐ I want to hear details only in certain situations, such as when tests are abnormal or when treatment decisions need to be made.
   ☐ I want to hear as many details as possible in all situations relating to my cancer and its treatment.

2. How *important* is it for you to know about **the likely outcome of your cancer over time** (i.e. your prognosis)? *Please check one.*

   ☐ Extremely important
   ☐ Very important
   ☐ Somewhat important
   ☐ A little important
   ☐ Not at all important

3. All things considered, how do you feel about the amount of information you know about **the likely outcome of your cancer over time** (i.e. your prognosis)? *Please check one.*

   ☐ I wish I had more information about my prognosis.
   ☐ I now have about the right amount of information.
   ☐ I wish I had less information about my prognosis.

4. How would you rate the quality of the information you have been given **by your oncologist about the likely outcome of your cancer over time** (i.e. your prognosis)? *Please check one.*

   ☐ Excellent
   ☐ Good
   ☐ Satisfactory
   ☐ Fair
   ☐ Poor

5. How would you describe your **current disease status**?

   ☐ Curable
   ☐ Likely Curable
   ☐ Unlikely Curable

☐ Incurable

6. **How long** have you been aware of this information? __________ **(in months)**

7. How are you currently feeling about your **current disease status**?

0	1	2	3	4
Mostly At Peace	Somewhat At Peace	Neutral	Somewhat Distressed	Very Distressed

Psychiatric Information

Have you ever had any type of counseling or treatment for emotional problems/issues?

1. Yes____ 2. No____

a) If yes, what type of problem? Please check all that apply:

1. Coping with physical illness	____Current	____Past
2. Life Stressor	____Current	____Past
3. Depression	____Current	____Past
4. Anxiety	____Current	____Past
5. Family/Marital Issues	____Current	____Past
6. Bereavement	____Current	____Past
7. Other (explain)____________	____Current	____Past

b) Specify treatment:

1. Individual Therapy	____Current	____Past
2. Group Therapy	____Current	____Past
3. Family/Marital Therapy	____Current	____Past
4. Medication (specify)	____Current	____Past
5. Inpatient Hospitalization	____Current	____Past
6. Other (explain) ____________	____Current	____Past

c) Please describe treatment: ____

d) Frequency & duration:____

____

FACIT – Spiritual Well-Being Scale (Version 4)

Below is a list of statements that other people with your illness have said are important. By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

		Not at all	A little bit	Some-what	Quite a bit	Very much
1.	I feel peaceful	0	1	2	3	4
2.	I have a reason for living	0	1	2	3	4
3.	My life has been productive	0	1	2	3	4
4.	I have trouble feeling peace of mind	0	1	2	3	4
5.	I feel a sense of purpose in my life	0	1	2	3	4
6.	I am able to reach down deep into myself for comfort	0	1	2	3	4
7.	I feel a sense of harmony within myself	0	1	2	3	4
8.	My life lacks meaning and purpose	0	1	2	3	4
9.	I find comfort in my faith or spiritual beliefs	0	1	2	3	4
10.	I find strength in my faith or spiritual beliefs	0	1	2	3	4
11.	My illness has strengthened my faith or spiritual beliefs	0	1	2	3	4
12.	I know that whatever happens with my illness, things will be okay	0	1	2	3	4

LIFE ATTITUDE PROFILE-REVISED (LAP-R)

This questionnaire contains a number of statements related to opinions and feelings about you and life in general. Read each statement carefully, then indicate the extent to which you agree or disagree by checking one of the alternative boxes provided. For example, if you **STRONGLY AGREE**, check the box under **STRONGLY AGREE** following the statement. If you **MODERATELY DISAGREE**, check **MODERATELY DISAGREE**. If you are **UNDECIDED**, check **UNDECIDED**. Try to use the undecided category sparingly.

		STRONGLY AGREE	AGREE	MODERATELY AGREE	UNDECIDED	MODERATELY DISAGREE	DISAGREE	STRONGLY DISAGREE
1.	My past achievements have given my life meaning and purpose.							
2.	In my life I have very clear goals and aims							
3.	I regard the opportunity to direct my life as very important.							
4.	I seem to change my main objectives in life.							
5.	I have discovered a satisfying life purpose.							
6.	I feel that some element which I can't quite define is missing from my life.							
7.	The meaning of life is evident in the world around us.							
8.	I think I am generally much less concerned about death than those around me.							
9.	I feel the lack of and a need to find a real meaning and purpose in my life.							
10.	New and different things appeal to me.							
11.	My accomplishments in life are largely determined by my own efforts.							
12.	I have been aware of an all powerful and consuming purpose towards which my life has been directed.							
13.	I try new activities or areas of interest and then these soon lose their attractiveness.							

		STRONGLY AGREE	AGREE	MODERATELY AGREE	UNDECIDED	MODERATELY DISAGREE	DISAGREE	STRONGLY DISAGREE
14.	I would enjoy breaking loose from the routine of life.							
15.	Death makes little difference to me one way or another.							
16.	I have a philosophy of life that gives my existence significance.							
17.	I determine what happens in my life.							
18.	Basically, I am living the kind of life I want to live.							
19.	Concerning my freedom to make my choice, I believe I am absolutely free to make all life choices.							
20.	I have experienced the feeling that while I am destined to accomplish something important, I cannot put my finger on just what it is.							
21.	I am restless.							
22.	Even though death awaits me, I am not concerned about it.							
23.	It is possible for me to live my life in terms of what I want to do.							
24.	I feel the need for adventure and “new worlds to conquer”.							
25.	I would neither fear death nor welcome it.							
26.	I know where my life is going in the future.							
27.	In thinking of my life, I see a reason for my being here.							
28.	Since death is a natural aspect of life, there is no sense worrying about it.							
29.	I have a framework that allows me to understand or make sense of my life.							
30.	My life is in my hands and I am in control of it.							

		STRONGLY AGREE	AGREE	MODERATELY AGREE	UNDECIDED	MODERATELY DISAGREE	DISAGREE	STRONGLY DISAGREE
31.	In achieving life's goals, I have felt completely fulfilled.							
32.	Some people are very frightened of death, but I am not							
33.	I daydream of finding a new place for my life and a new identity.							
34.	A new challenge in my life would appeal to me now.							
35.	I have the sense that parts of my life fit together in a unified pattern.							
36.	I hope for something exciting in the future.							
37.	I have a mission in life that gives me a sense of direction.							
38.	I have a clear understanding of the ultimate meaning of life.							
39.	When it comes to important life matters, I make my own decisions.							
40.	I find myself withdrawing from life with an "I don't care" attitude.							
41.	I am eager to get more out of life than I have so far.							
42.	Life to me seems boring and uneventful.							
43.	I am determined to achieve new goals in the future.							
44.	The thought of death seldom enters my mind.							
45.	I accept personal responsibility for the choices I have made in my life.							
46.	My personal existence is orderly and coherent.							
47.	I accept death as another life experience.							
48.	My life is running over with exciting good things.							

Religiosity Questionnaire

		No	**Not Certain**	**Yes**
1.	I enjoy reading about my religion	☐	☐	☐
2.	I go to my place of worship because it helps me make friends	☐	☐	☐
3.	It is important to me to spend time in private thought and prayer	☐	☐	☐
4.	I have often had a strong sense of God’s presence	☐	☐	☐
5.	I pray mainly to gain relief and protection	☐	☐	☐
6.	I try hard to live all my life according to my religious beliefs	☐	☐	☐
7.	What religion offers me most is comfort in times of trouble and sorrow	☐	☐	☐
8.	My religion is important because it answers many questions about the meaning of life	☐	☐	☐
9.	Prayer is for peace and happiness	☐	☐	☐
10.	I go to my place of worship mostly to spend time with my friends	☐	☐	☐
11.	My whole approach to life is based on my religion	☐	☐	☐
12.	I go to my place of worship mainly because I enjoy seeing people I know there	☐	☐	☐

HADS

Instructions: Read each item and please ***circle*** the answer which comes closest to how you have been feeling, on the average, in the past week. Don't take too long over your answers; your immediate reaction to each item will probably be more accurate than a long thought out response.

1. I feel tense or 'wound up':
a. Most of the time
b. A lot of the time
c. From time to time, occasionally
d. Not at all

2. I still enjoy the things I used to enjoy:
a. Definitely as much
b. Not quite so much
c. Only a little
d. Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen:
a. Very definitely and quite badly
b. Yes, but not too badly
c. A little, but it doesn't worry me
d. Not at all

4. I can laugh and see the funny side of things:
a. As much as I always could
b. Not quite so much now
c. Definitely not so much now
d. Not at all

5. Worrying thoughts go through my mind:
a. A great deal of the time
b. A lot of the time
c. From time to time but not too often
d. Only occasionally

6. I feel cheerful:
a. Not at all
b. Not often
c. Sometimes
d. Most of the time

7. I can sit at ease and feel relaxed:
a. Definitely
b. Usually
c. Not often
d. Not at all

8. **I feel as if I am slowed down:**
   a. Nearly all the time
   b. Very often
   c. Sometimes
   d. Not at all

9. **I get a sort of frightened feeling like 'butterflies' in the stomach:**
   a. Not at all
   b. Occasionally
   c. Quite often
   d. Very often

10. **I have lost interest in my appearance:**
   a. Definitely
   b. I don't take as much care as I should
   c. I may not take quite as much care
   d. I take just as much care as ever

11. **I feel restless as if I have to be on the move:**
   a. Very much indeed
   b. Quite a lot
   c. Not very much
   d. Not at all

12. **I look forward with enjoyment to things:**
   a. As much as ever I did
   b. Rather less than I used to
   c. Definitely less than I used to
   d. Hardly at all

13. **I get sudden feelings of panic:**
   a. Very often indeed
   b. Quite often
   c. Not very often
   d. Not at all

14. **I can enjoy a good book or radio or TV program:**
   a. Often
   b. Sometimes
   c. Not often
   d. Very seldom

LOT-R

Please be as honest and accurate as you can throughout. Try not to let your response to one statement influence your responses to other statements. There are no "correct" or "incorrect" answers. Answer according to your own feelings, rather than how you think "most people" would answer.

	Agree a lot	**Agree a little**	**Neither Agree nor Disagree**	**Disagree a little**	**Disagree a lot**
1. In uncertain times, I usually expect the best.	5	4	3	2	1
2. It's easy for me to relax.	5	4	3	2	1
3. If something can go wrong for me, it will.	1	2	3	4	5
4. I'm always optimistic about my future.	5	4	3	2	1
5. I enjoy my friends a lot.	5	4	3	2	1
6. It's important for me to keep busy.	5	4	3	2	1
7. I hardly ever expect things to go my way.	1	2	3	4	5
8. I don't get upset too easily.	5	4	3	2	1
9. I rarely count on good things happening to me	1	2	3	4	5
10. Overall, I expect more good things to happen to me than bad.	5	4	3	2	1

HAI

Please circle the item that best describes how you have been feeling over the past few days.

1. 0 I don’t feel discouraged about my future.
1 I sometimes feel discouraged about my future.
2 I often feel discouraged about my future.

2. 0 I don’t have the inner strength to keep fighting this illness.
1 I don’t know if I have the inner strength to keep fighting this illness.
2 I have the inner strength to keep fighting this illness.

3. 0 It is hard to think about anything besides my illness.
1 Sometimes I can think about things other than my illness.
2 I can put my illness out of my mind most of the time.

4. 0 I don’t let myself feel hopeless.
1 I try to stay hopeful but sometimes I can’t.
2 I can't help feeling hopeless much of the time.

5. 0 I dread every day.
1 Sometimes it’s hard for me to face the day.
2 I usually look forward to each day.

6. 0 I feel a sense of control over my life.
1 I feel in control of some parts of my life.
2 I have no control over my life.

7. 0 I have nothing to look forward to.
1 I am looking forward to some things
2 I am looking forward to many things.

8. 0 I almost always feel hopeful.
1 Sometimes I feel hopeless but then it passes.
2 I almost always feel hopeless.

McGILL QUALITY OF LIFE QUESTIONNAIRE

The questions in this questionnaire begin with a statement followed by two opposite answers. Numbers extend from one extreme answer to its opposite. Please *circle the number between 0 and 10 which is most true for you.* There are no right or wrong answers. Completely honest answers will be most helpful.

Example:

I am hungry...	0	1	2	3	4	5	6	7	8	9	10
not at all									extremely		

If you are not even a little bit hungry, you would circle 0.
If you are a little hungry (you just finished a meal but still have room for dessert), you might circle 1, 2, or 3.
If you are feeling moderately hungry (because mealtime is approaching), you might circle 4, 5, or 6.
If you are very hungry (because you haven't eaten all day), you might circle 7, 8, or 9.
If you are extremely hungry, you would circle 10.

BEGIN HERE:

IT IS VERY IMPORTANT THAT YOU ANSWER ALL QUESTIONS FOR HOW YOU HAVE BEEN FEELING *JUST IN THE PAST TWO (2) DAYS.*

PART A

Considering all parts of my life- physical, emotional, social, spiritual, and financial- over the past two (2) days the quality of my life has been:

very bad	0	1	2	3	4	5	6	7	8	9	10	excellent

Please continue on the next page…

PART B: Physical Symptoms

(1) For the three (3) questions in Part “B”, please list the three (3) PHYSICAL SYMPTOMS which have been the biggest problem for you over the past two (2) days. (Some examples are: pain, tiredness, weakness, nausea, vomiting, constipation, diarrhea, trouble sleeping, shortness of breath, lack of appetite, sweating. Feel free to refer to others if necessary).

(2) Circle the number which best shows how big of a problem each one has been for you OVER THE PAST TWO (2) DAYS.

(3) If, over the past two (2) days, you had NO physical symptoms or only one or two, answer for each of the symptoms you have had and write “none” for the extra questions in Part B, then continue with Part C.

1. Over the past two (2) days, one troublesome symptom has been:

____

(write symptom)

0 1 2 3 4 5 6 7 8 9 10

No Problem Tremendous Problem

2. Over the past two (2) days, another troublesome symptom has been:

____

(write symptom)

0 1 2 3 4 5 6 7 8 9 10

No Problem Tremendous Problem

3. Over the past two (2) days, a third troublesome symptom has been:

____

(write symptom)

0 1 2 3 4 5 6 7 8 9 10

No Problem Tremendous Problem

4. Over the past two (2) days I have felt:

0 1 2 3 4 5 6 7 8 9 10

Physically Terrible Physically Well

PART C

Please choose the number which best describes your feelings and thoughts OVER THE PAST TWO (2) DAYS.

5. Over the past two (2) days, I have been depressed:

0 1 2 3 4 5 6 7 8 9 10

Not at all Extremely

6. Over the past two (2) days, I have been nervous or worried:

0 1 2 3 4 5 6 7 8 9 10

Not at all Extremely

7. Over the past two (2) days, how much of the time did you feel sad?

0 1 2 3 4 5 6 7 8 9 10

Never Always

8. Over the past two (2) days, when I thought of the future, I was:

0 1 2 3 4 5 6 7 8 9 10

Not afraid Terrified

9. Over the past two (2) days, my life has been:

0 1 2 3 4 5 6 7 8 9 10

Utterly meaningless and without purpose Very purposeful and meaningful

10. Over the past two (2) days, when I thought about my whole life, I felt that in achieving life goals I have:

0 1 2 3 4 5 6 7 8 9 10

Made no progress whatsoever Progressed to complete fulfillment

11. Over the past two (2) days, when I thought about my life, I felt that my life to this point has been:

0 1 2 3 4 5 6 7 8 9 10

Completely worthless Very worthwhile

12. Over the past two (2) days, I have felt that I have :

0 1 2 3 4 5 6 7 8 9 10

No control over
my life

Complete control
over my life

13. Over the past two (2) days, I felt good about myself as a person.

0 1 2 3 4 5 6 7 8 9 10

Completely disagree

Completely agree

14. To me, the past two (2) days were:

0 1 2 3 4 5 6 7 8 9 10

A burden

A gift

15. Over the past two (2) days, the world has been:

0 1 2 3 4 5 6 7 8 9 10

An impersonal and
unfeeling place

Caring and responsive
to my needs

16. Over the past two (2) days, I have felt supported:

0 1 2 3 4 5 6 7 8 9 10

Not at all

Completely

SAHD

People who have chronic illnesses are sometimes concerned about the avoidance of prolonged suffering. Please circle “T” for each statement that applies to you and “F” for each statement that does not apply to you.

T F (1) I feel confident that I will be able to cope with the emotional stress of my illness.

T F (2) I expect to suffer a great deal from emotional problems in the future because of my illness.

T F (3) My illness has drained me so much that I do not want to go on living.

T F (4) I am seriously considering asking my doctor for help in ending my life.

T F (5) Unless my illness improves I will consider taking steps to end my life.

T F (6) Dying seems like the best way to relieve the pain and discomfort my illness causes.

T F (7) Despite my illness my life still has purpose and meaning.

T F (8) I am careless about my treatment because I want to let the disease run its course.

T F (9) I want to continue living no matter how much pain or suffering my disease causes.

T F (10) I hope my disease will progress rapidly because I would prefer to die rather than continue living with this illness.

T F (11) I have stopped treatment for my illness because I would prefer to let the disease run its course

T F (12) I enjoy my present life even with my illness and would not consider ending it.

T F (13) Because my illness cannot be cured I would prefer to die sooner rather than later.

T F (14) Dying seems like the best way to relieve the emotional suffering my illness causes.

T F (15) Doctors will be able to relieve most of the discomfort my illness causes.

T F (16) Because of my illness the idea of dying seems comforting.

T F (17) I expect to suffer a great deal from physical problems in the future because of my illness.

T F (18) I plan to end my own life when my illness becomes too much to bear.

T F (19) I am aggressively pursuing all possible treatments because I'll do anything possible to continue living.

T F (20) I am able to cope with the symptoms of my illness and have no thoughts of ending my life.

MEMORIAL SYMPTOM ASSESSMENT SCALE – Short Form [MSAS-SF]

I. INSTRUCTIONS: Below is a list of symptoms. If you had the symptom DURING THE PAST WEEK, please check Yes. If you did have the symptom, please check the box that tells us how much the symptom DISTRESSED or BOTHERED you.

Check all the symptoms you have had during the PAST WEEK.		→ → IF YES: How much did it DISTRESS or BOTHER you?					
		Yes [✓]	Not at All [0]	A little Bit [1]	Some-what [2]	Quite a Bit [3]	Very much [4]
1	Difficulty concentrating						
2	Pain						
3	Lack of energy						
4	Cough						
5	Changes in skin						
6	Dry mouth						
7	Nausea						
8	Feeling drowsy						
9	Numbness/tingling in hands and feet						
10	Difficulty sleeping						
11	Feeling bloated						
12	Problems with urination						
13	Vomiting						
14	Shortness of breath						
15	Diarrhea						
16	Sweats						
17	Mouth sores						
18	Problems with sexual interest or activity						
19	Itching						
20	Lack of appetite						
21	Dizziness						
22	Difficulty swallowing						
23	Change in the way food tastes						
24	Weight loss						

MEMORIAL SYMPTOM ASSESSMENT SCALE – Short Form [MSAS-SF]

II. INSTRUCTIONS: Below is a list of symptoms. If you had the symptom DURING THE PAST WEEK, please check Yes. If you did have the symptom, please check the box that tells us how much the symptom DISTRESSED or BOTHERED you.

Check all the symptoms you have had during the PAST WEEK.		→ → IF YES: How much did it DISTRESS or BOTHER you?					
		Yes [✓]	Not at All [0]	A little Bit [1]	Some-what [2]	Quite a Bit [3]	Very much [4]
25	Hair loss						
26	Constipation						
27	Swelling of arms or legs						
28	“I don’t look like myself”						
29	If you had any other symptoms during the PAST WEEK, please list them below, and indicate how much the symptom DISTRESSED or BOTHERED you. a. ______________________________ b. ______________________________						

II. Below are other commonly listed symptoms. Please indicate if you have had the symptom DURING THE PAST WEEK, and if so, how OFTEN it occurred.

Check all the symptoms you have had during the PAST WEEK.		→ → IF YES: How often did it occur?				
		Yes [✓]	Rarely [1]	Occasionally [2]	Frequently [3]	Almost Constantly [4]
30	Feeling Sad					
31	Worrying					
32	Feeling Irritable					
33	Feeling Nervous					

Duke- UNC Functional Social Support Questionnaire

I get...

Much less than I would like **As much as I would like**

1. Visits from friends and relatives… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
2. Help… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
3. Help with money in an emergency… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
4. Praise for a good job… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
5. People who care what happens to me… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
6. Love and affection … 0. . . . . . 1. . . . . . 2. . . . . 3. 4
7. Telephone calls from people I know… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
8. Chances to talk to someone about problems at work or with my housework … 0. . . . . . 1. . . . . . 2. . . . . 3. 4
9. Chances to talk to someone I trust about my personal and family problems… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
10. Chances to talk about money matters… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
11. Invitations to go out and do things with other people… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
12. Useful advice about important things in life… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
13. Help when I need transportation… 0. . . . . . 1. . . . . . 2. . . . . 3. 4
14. Help when I am sick in bed … 0. . . . . . 1. . . . . . 2. . . . . 3. 4

UBQ

Sometimes individuals faced with the threat of cancer become more reflective and think about things that feel unfinished or unresolved in their lives. These can be things they wish to do or accomplish in a certain area of their lives (e.g., relationships, work, projects, travel), or perhaps things they wish to repair or make amends for in a relationship, but have not yet done. Do you feel that anything is unfinished or unresolved in your life? (Please circle yes or no.)

Yes - 1

No - 0

If yes, please describe the most troubling example of what feels unfinished or unresolved in your life:

____

____

____

____

If you provided an example, please rate how distressed you are now by this unfinished or unresolved matter by circling the number on the scale below, where 10 is most distressed.

1	2	3	4	5	6	7	8	9	10
Not at all distressed									Extremely distressed

PA Clinician Rating (Part A)

Some people think about how much time they have left…Do you every think about this?
If so, what do you think about?

Has your physician discussed this with you? What have the doctors told you about this?

Fill in based on patient response:

_____ Years

_____ Months

_____ I don't know

_____ I have not discussed it with my doctor

_____ I don't want to talk about it

_____ I don't want to think about it

_____ Other ____

Clinician Rating of Prognostic Awareness:

_____ 1 = No Acknowledged Awareness
(i.e., the patient reports no understanding that their disease is incurable)

_____ 2 = Limited Awareness
(i.e., the patient reports some understanding of terminal prognosis but has an unrealistic expectation of life expectancy)

_____ 3 = Full Awareness
(i.e., the patient has awareness that they have incurable disease and a shortened life expectancy)

How confident are you in your ratings?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

PA Clinician Self-Evaluation (Part B)

Study ID #: __________

Did you use the prompts?			YES	NO

If yes, how comfortable were you with using the prompts?

Not at all	Mildly	Somewhat	Moderately	Very

If no, why?

☐ Patient was too distressed

☐ PA emerged naturally in session

☐ Not clinically appropriate (explain: ____)

☐ Other____

PA was assessed in (please circle):

Session 1 Session 2 Both

How comfortable were you in assessing PA?

Not at all	Mildly	Somewhat	Moderately	Very

How distressed was the patient by this conversation? (please circle)

Not at all	Mildly	Somewhat	Moderately	Very

How receptive was the patient to this conversation? (please circle)

Not at all	Mildly	Somewhat	Moderately	Very

How distressing was this conversation to you? (please circle)

Not at all	Mildly	Somewhat	Moderately	Very

Appendix E.

WORKING ALLIANCE INVENTORY-CLIENT FORM (Assessed as part of T2 battery)

Below is a list of statements about your relationship with your therapist. Consider each item carefully and indicate your level of agreement for each of the following items.

	Does not correspond at all ▼			Corresponds moderately ▼			Corresponds exactly ▼
1. My therapist and I agree about the things I will need to do in therapy to help improve my situation.........	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …
2. What I am doing in therapy gives me new ways of looking at my problem...	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …
3. I believe my therapist likes me......	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …
4. My therapist does not understand what I am trying to accomplish in therapy...	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …
5. I am confident in my therapist's ability to help me...........................	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …
6. My therapist and I are working towards mutually agreed upon goals..	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …
7. I feel that my therapist appreciates me..	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …
8. We agree on what is important for me to work on................................	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …
9. My therapist and I trust one another..	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …

10. My therapist and I have different ideas on what my problems are……	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …
11. We have established a good understanding of the kind of changes that would be good for me	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …
12. I believe the way we are working with my problem is correct…………	… ☐ 1 …	… ☐ 2 …	… ☐ 3 …	… ☐ 4 …	… ☐ 5 …	… ☐ 6 …	… ☐ 7 …