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Newly diagnosed pediatric oncology patients and their families: the effect of family therapy on anxiety and depression

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Newly diagnosed pediatric oncology patients and their families: the effect of family
therapy on anxiety and depression

by

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Newly diagnosed pediatric oncology patients and their families: the effect of family therapy on anxiety and depression

by

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The proposed study is a preliminary investigation of a hypothesized relationship between family therapy and levels of child patient and parent anxiety and depression. Currently, medical practice does not include mental health services and familial support to oncology patients in typical treatment protocol. While anxiety and depression appear to be present during all phases of cancer, providing family therapy at the time of diagnosis is warranted as symptom alleviation at this juncture may mitigate these symptoms throughout subsequent phases and potentially decrease somatic difficulties. Research questions will be addressed by analyzing data, including scores on measures of anxiety and depression. Statistical analyses will include two and three-way analyses of variance (ANOVA) and repeated measures multivariate analysis of variance (MANOVA).
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Introduction

The survival and well being of newly diagnosed pediatric oncology patients is an issue of constant and substantial concern. Particularly in cases of childhood cancer, the illness impacts both the patient and the family system, drastically escalating anxiety and depression of family members. Increasingly effective medical treatments are often intensive and complex, focusing directly on the child patient. While extant literature demonstrates that cancer patients are faced with psychological distress, much of the research has focused on adult cancer patients. Studies that have investigated the impact of parental cancer on children and the family have found a diversity of results, indicating negative changes in emotional, social, behavioral, cognitive and physical functioning of children (Visser, Huizinga, van der Graff, Hoekstra, Hoeskstra-Weebers, 2004).

The American Cancer Society (2009) indicates that cancer rates in children over the past 30 years have increased, while mortality rates have decreased. As a result of increased recovery, research on cancer youth has primarily focused on survivors. To date, there is no empirical research that investigates the effect of family therapy on levels of anxiety and depression of newly diagnosed childhood cancer patients and their parents. Given the aggressive and arduous medical treatments that these child patients face, such research may provide a rationale to include family therapy in typical treatment protocol.
Integrative Analysis and Interpretation

The purpose of this proposal is to expand the knowledge base specific to anxiety and depression in families associated with a specific disease-related group: namely, pediatric oncology. The goal of this integrative analysis is to evaluate relevant literature and present an overview of pertinent information related to the topic. The analysis begins with an introduction to pediatric oncology including a description of acute lymphocytic leukemia. The adult oncology literature is subsequently utilized to inform the dearth of pediatric oncology research. Finally, a discussion regarding the ways in which cancer affects the entire family system followed by an appraisal of family interventions is presented. This underlies the rationale for the inclusion of family therapy in the routine treatment of pediatric cancer.

Pediatric Cancer

The American Cancer Society (2009) estimates that 10,730 new cases of pediatric cancer are expected to occur in children aged 0-14 in 2009. While childhood cancer is still considered rare, it remains the second leading cause of death in children; it is expected that approximately 1,490 deaths will occur because of it this year alone. However, incidence rates from the National Cancer Institute and death rates from the National Center for Health Statistics indicate increasing survival and decreasing fatality of pediatric patients. Dramatic progress in the treatment of childhood cancer has shifted over the last thirty years such that the 5-year survival rate for childhood cancer is currently 80% (Riese, Melbert, Krapcho, Stinchcomb, Howlander, Horner et al., 2008). Primary advances responsible for this increase in childhood survival are earlier detection,
increased centralization of care, pediatric subspecialties, and implementation of multimodal interventions (Kelly & Gibson, 2008; Reaman, 2004; Boman & Bodegard, 2000). Consequently, research has seen a shift in focus from effectiveness of cancer treatment in children to effectiveness of treatment of associated symptom distress (Reaman, 2002; Woodgate, Denger, & Yanofsky, 2003).

Cancer is generally defined as an uncontrollable growth of abnormal cells in any given part of the body. Typically, cells in the body divide and atrophy in a methodical manner. While damage to cell DNA is usually self-corrected, cancer develops when abnormal or damaged cells are not repaired. Different types of cancers act differently in the body. Some form tumors, while others involve the blood; others progress at different rates and respond to different treatments. Contingent upon the type and stage of cancer, pediatric cancer treatment options include chemotherapy, surgical removal of abnormal cells, bone marrow transplantation, radiation and/or some combination treatments. Table 1 details childhood cancer types, location in the body, typical treatment, and prognosis.

<table>
<thead>
<tr>
<th>Type</th>
<th>Location in the body</th>
<th>Typical primary treatment</th>
<th>Prognosis (5 year survival)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute lymphocytic leukemia</td>
<td>Blood and bone marrow</td>
<td>Chemotherapy</td>
<td>73%</td>
</tr>
<tr>
<td>Myelogeneous leukemia</td>
<td>Blood and bone marrow</td>
<td>Chemotherapy</td>
<td>46%</td>
</tr>
<tr>
<td>Brain cancer</td>
<td>Brain</td>
<td>Surgery</td>
<td>65%</td>
</tr>
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Table 1 (continued)

<table>
<thead>
<tr>
<th>Nervous system cancer</th>
<th>Central nervous system</th>
<th>Radiation therapy</th>
<th>13%</th>
</tr>
</thead>
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<tr>
<td>Neuroblastoma</td>
<td>Adrenal glands</td>
<td>Surgery</td>
<td>30%</td>
</tr>
<tr>
<td>Non-Hodgkin lymphoma</td>
<td>Lymph system</td>
<td>Chemotherapy</td>
<td>76%</td>
</tr>
<tr>
<td>Hodgkin lymphoma</td>
<td>Bone marrow</td>
<td>Chemotherapy, radiation</td>
<td>93%</td>
</tr>
<tr>
<td>Rhabdomyosarcoma</td>
<td>Head and neck around eyes</td>
<td>Combo of surgery, chemotherapy and radiation</td>
<td>50%</td>
</tr>
<tr>
<td>Retinoblastoma</td>
<td>Eyes</td>
<td>Surgery, light coagulation, radiation, chemotherapy, cryotherapy</td>
<td>80-90%</td>
</tr>
<tr>
<td>Osteosarcoma</td>
<td>Soft tissue</td>
<td>Neoajuvant</td>
<td>92%</td>
</tr>
</tbody>
</table>

The most common type of childhood cancer is leukemia. It accounts for 30% of cases, with acute lymphocytic leukemia (ALL) being the most common type (American Cancer Society, 2009). This review highlights ALL because the sample specific to the study will be limited to children with this type of cancer. Among individuals younger than 15 years of age, ALL represents 23 percent of cancer diagnoses and occurs in about
one of every 29,000 children in the United States each year (National Cancer Institute, 2009). To date, the exact cause of ALL remains unknown. In ALL, abnormal lymphoblasts proliferate in the blood-forming tissues and are too fragile and immature to exhibit the infection-fighting capacity of normal white blood cells (National Cancer Institute, 2009). The growth of these lymphoblasts is excessive as abnormal cells replace the normal cells in bone marrow. Anemia, neutropenia, and thrombocytopenia result as the bone marrow loses its ability to maintain normal levels of red blood cells, white blood cells, and platelets. As leukemic cells spread to the central nervous system, vomiting, headache, seizures, coma, vision alterations, or cranial nerve palsies may occur (Kyle & Kyle, 2007).

Most children will achieve initial remissions if appropriate treatment is given. Among other factors, prognosis is based upon the white blood cell count at diagnosis, the type of cytogenetic factors, and the age at diagnosis (National Cancer Institute, 2009). Generally, children ages 2 to 10 years at diagnosis have the most positive prognosis while infants less than 12 months of age at diagnosis face a poorer prognosis. The overall cure rate of ALL is 65 to 75 percent and relapse is rare after 7 years from diagnosis. Today, about 73 percent of children with ALL live five years or more (Kyle, et al., 2007).

A majority of pediatric oncology patients are treated at centers associated with the Children’s Oncology Group, the world’s largest cancer research organization. Because childhood cancer is less common than cancers in adulthood (MD Anderson Cancer Center, 2009), pediatric oncology treatment is limited to these specialized medical centers (Woznick & Goodheart, 2002). As such, considerable financial expenditure and
emotional strain is experienced by the families who are at times required to travel hundreds of miles in order to receive appropriate treatment for their children. More specifically, these families face increased burden as they leave behind their support networks of relatives and friends. Additional challenges are experienced as families are faced with decisions about starting conventional treatment or participating in clinical trials. This process is further complicated by the practical need to cover the costs of expensive treatments, which may require parents to investigate complex insurance plans or public assistance programs. Coupled with alterations in equilibrium, roles, responsibilities and relationships of the family unit, diagnosis marks the beginning of significant long-term adjustment (Langton, 2000).

Cancer treatment has pervasive detrimental effects on a child. Delays in speech development, motor skills and social skills (Lingnell & Dunn, 1999; Woznick & Goodheart, 2002) as well as various physical symptoms such as fatigue, pain, and nausea are all common (Eyre, Lange, & Morris, 1997). Managing medical treatment, disease progression, and physical symptom distress are obvious and critical components of oncological intervention. However, dealing with the cascade of emotions triggered by a cancer diagnosis is equally important to a healthy recovery. While substantial evidence demonstrates that individuals with cancer are faced with psychological distress, empirical studies are limited to adult oncology patients. Because research in the area of pediatric oncology is limited, existing studies in adult oncology are used to inform this gap in the literature.
Empirical evidence indicates that adult cancer patients experience psychological distress in various multifaceted manifestations (Galuszko, 1996; Newport & Nemeroff, 1998; Sellick & Edwardson, 2007; Herschbach, Book, Brandl, Keller, Lindena, Neuwöhner, & Marten-Mittag, 2008). Among these reactions, anxiety and depression are both well documented and among the most common, in both patients and caregivers (Grov, Dahl, Moum, & Fossa, 2005; Carlson, Angen, Cullum, Goodey, Koopmans, Lamont, MacRae, Martin, Pelletier, Robinson, Simpson, Speca, Tillotson, Bultz, 2004). While anxiety and depression have been observed to occur throughout treatment, diagnosis often heightens distress (Stefanek, Derogatis, Shaw, 1987). Further, increasingly effective cancer treatments are often intensive and complex, and may perpetuate persistent anxiety and depression through, and sometimes beyond, successful medical intervention (Cordova, Andrykowski, Kenady, McGrath, & Sloan, 1995). While many studies have explored the incidence of depression and anxiety in adult cancer patients, estimates of their prevalence vary widely (Massie, 2004; Van’t Spijker, Trijsburg, Duivenvoorden, 1997). Often, distressed patients remain unidentified (Fallowfield, Ratcliffe, Jenkins, Saul, 2001), resulting in lack of treatment in up to 90% of cases (Keller, Sommerfeldt, Fischer, Knight, Riesbeck, Lowe, et al., 2004).

**Adult Cancer and Patient Anxiety**

In general, uncertainty about the cause, course of treatment and outcome of cancer is the central source of confusion, stress and anxiety once a diagnosis is confirmed (Harding, 2000; Halford et al., 2000; Sherman & Simonton, 2001; Veach & Nicholas,
Further, Nordin and Glimelius (1999) illustrated that if anxiety is present immediately after diagnosis, it is predictive of persistent anxiety through subsequent cancer phases. During the course of medical treatment, anxiety may exacerbate somatic symptoms of patients; however, group psychotherapy appears to considerably assuage these symptoms (Forester et al., 1993). Additionally, a rise in anxiety once treatment is complete has been identified and the presence of anxiety even appears to affect the transition from hospital care to general practice (Thomas, Glynne-Jones, Chait, & Marks, 1997). While anxiety does appear to diminish years after diagnosis (Fallowfield et al., 1994), Loge (1997) established that even after intervention, anxiety levels appear to remain higher than in the general population.

**Adult Cancer and Patient Depression**

The prevalence of depressive disorders in adult cancer patients has been demonstrated in numerous studies (Akechi et al., 2002; Okuyama, Akechi, & Kugaya, 2000; Akeichi et al., 2000). Among psychiatric disorders reported in cancer patients, it is estimated that depression is the most common (Akechi et al., 2002; Breitbart et al., 2000) and more frequently experienced by terminally ill and advanced cancer patients (Kugaya et al., 1999). Evidence indicates that more severe depression may be even associated with faster progression of cancer and higher levels of physical symptoms such as pain (Spiegel, Sands, & Koopman, 1994; Spiegel et al., 1996). Further, Temel et al. (2006) found that depression in newly diagnosed patients was related to a lower 6-month survival rate.
The Oncology Patient and Family System

The impact of cancer on relatives of adult patients has been widely explored (Cohen, Kuten, 2006) and studies that have investigated the impact of parental cancer on children and families have found a diversity of results (Visser et al., 2004). More specifically, in cases of adult cancer, family relationships have been shown to affect patient adjustment (Friedman et. al, 1997; Spiegel, Bloom, & Gottheil, 1983) and psychological distress has been identified among all family members (Ferrell, Ervin, Smith, Marek, & Melancon, 2002; Northouse, Mood, Templin, Mellon & George, 2000; Omne-Ponten, Holmberg, Bergstrom, Sjoden, & Burns, 1993).

Specific to pediatric oncology, both the child patient and the entire family system are affected when confronted with potentially life threatening acute illness (Houtzager, B., Grootenhius, M., & Last, B., 1999); intense stress and anxiety are likely to be experienced by all family members (Pinkerton, Cushing & Sepion, 1994). For example, siblings may become anxious about catching the disease or may feel somehow responsible for causing the illness (Adams & Deveau, 1984; Woznick & Goodheart, 2002). Not only do the child’s symptoms affect the family (Woodgate & Kristjanson, 1996), but parental distress, interactions, responses, and patterns of communication significantly affect levels of child distress and psychological adjustment as well (Dahlquist et al., 2002; Naber, 1995; Sawyer, Streiner, Antoniou, Toogood, & Rice, 1998; Vance & Eiser, 2004).
Family Therapy

Substantial literature demonstrates the efficacy of family therapy for a broad range of psychological problems and distress (Asen, 2002); family interventions specific to anxiety and depression have been assessed in various studies (Barrett & Shortt, 2003; Moore & Carr, 2000; Northey, Wells, Silverman & Bailey, 2003). While a complete historical review of family therapy models and perspectives is beyond the scope of this analysis, a relevant exploration is presented below.

As a whole, the theoretical framework of family therapy utilizes ideas from communications theory, systems theory and cybernetics. Taken together, these principles serve as the basis for healthy adaptation in a family system (Carr, 2006). Basic to family theory and fundamental to this investigation is the concept of a “family life cycle”. Childhood cancer can be a viewed non-normative life event and atypical adversity in a family’s development (Woznick & Goodheart, 2002). At diagnosis, parents are confronted with the possibility that their child’s death may precede their own, a clear divergence from the expectations of the typical family life cycle (McGoldrick & Walsh, 1988). Consequently, families must discover how to manage the inherent challenges and effectively navigate coping. Family therapy may facilitate adaptation during this disruption in the life cycle.

Research in the area family intervention of pediatric oncology has been limited to two studies. A one session, family-systems multi-group intervention has been shown to reduce posttraumatic stress symptoms across family members of adolescent cancer survivors (Kazak, Alderfer, Streisand, Simms, Rourke, Barakat, et al., 2004). In a
preliminary pilot study, Kazak et al. (2005) found that a cognitive behavioral family systems intervention reduced levels of posttraumatic stress and anxiety for parents of children with cancer. However, the sample in the study is limited to 19 families and the authors state, “this evaluation process is preliminary and awaits the results of a more rigorous evaluation in a larger randomized clinical trial.” Specific to this study, their three-session family intervention is highlighted and will be utilized as the family therapy intervention. The Surviving Cancer Competently Intervention Program-Newly Diagnosed (SCCIP-ND) is a manualized intervention specifically designed for families of newly diagnosed pediatric oncology patients. Currently, other evidence-based family interventions for pediatric oncology patients in treatment do not exist.

While clinical practice guidelines are beginning to suggest mental health services as supportive care for oncology, therapeutic treatment still remains a simple suggestion; no specific forms are recommended (Jacobson, 2008). Consideration of the significance of the diagnosis phase along with the systemic impact of pediatric cancer lends support for therapeutic intervention that takes into account the family as integral for the reduction of psychological distress.
Proposed Research Study

Statement of the Problem

The purpose of this study is to explore levels of anxiety and depression in newly diagnosed cases of pediatric cancer. The proposed study is a preliminary investigation of a hypothesized relationship between family therapy and levels of child patient and parent anxiety and depression. Currently, medical practice does not include mental health services and familial support to oncology patients in typical treatment protocol. This has resulted from the emphasis on the primary goals of keeping the child patient alive and eradicating malignancy. However, it has been established that psychological distress, including anxiety and depression, are prevalent among cancer patients. Further, it is recognized that cancer causes distress in both the child patient and their family members.

The theoretical framework of family therapy asserts that individuals in a family system influence and are influenced by all members of the system. As the whole of the family is seen as greater than the sum of its parts, simply addressing psychological distress in the oncology patient is ineffective and treatment should extend to the entire family system.

Family therapy has been shown to effectively treat psychological problems and it is posited that it is an ideal intervention for reduction of anxiety and depression at the time of diagnosis. Considering the increased rates of survival in pediatric oncology patients and the extensive impact of diagnosis on the family system, the evaluation of clinical family interventions is critical. This research was prompted by the recognition of the dearth of existing empirical research in this area. The current literature lacks reports of evidence-based family intervention research following pediatric cancer diagnosis;
studies on the subject are limited to survival populations. Further, there do not appear to be any randomized controlled studies that explore anxiety and depression in cases of newly diagnosed pediatric cancer. While anxiety and depression appear to be present during all phases of cancer, providing family therapy at the time of diagnosis is warranted as symptom alleviation at this juncture may mitigate these symptoms throughout subsequent phases and potentially decrease somatic difficulties.

Research Questions and Hypothesis

Test of Research Questions

For all analyses described in this section, an alpha level of 0.05 will be used unless otherwise stated.

Research Question 1

When compared to a minimal contact control group, does family therapy decrease levels of anxiety in pediatric ALL patients and their parents?

Hypothesis 1a. Patient anxiety levels in the family therapy group will be significantly lower post-intervention than patient anxiety levels in the minimal contact control group. Patient anxiety levels in the control group will either stay the same or increase.

Hypothesis 1b. Mother anxiety levels in the family therapy group will be significantly lower post-intervention than mother anxiety levels in the minimal contact control group. Mother anxiety levels in the control group will either stay the same or increase.
Hypothesis 1c. Post-intervention anxiety levels of fathers in the family therapy group will be significantly lower than anxiety levels of fathers in the minimal contact control group. Anxiety levels of fathers in the control group will either stay the same or increase.

Research Question 2

When compared to a minimal contact control group, does family therapy decrease levels of depression in pediatric ALL patients and their parents?

Hypothesis 2a. Patient levels of depression in the family therapy group will be significantly lower post-intervention than patient levels of depression in the minimal contact control group. Patient levels of depression in the control group will either stay the same or increase.

Hypothesis 2b. Post-intervention depression levels of mothers in the family therapy group will be significantly lower over time than depression levels of mothers in the minimal contact control group. Depression levels of mothers in the control group will either stay the same or increase.

Hypothesis 2c. Father levels of depression in the family therapy group will be significantly lower post-intervention than father levels of depression in the minimal contact control group. Father levels of depression in the control group will either stay the same or increase.

Research Question 3
Do pediatric ALL patients and their parents in the family therapy condition maintain decreased anxiety across time in comparison to the minimal contact control condition?

*Hypothesis 3a.* In comparison to the control condition, significantly lower levels of patient anxiety in the family therapy condition will be maintained post-treatment over time (3 months).

*Hypothesis 3b.* In comparison to the control condition, significantly lower levels of anxiety for mothers in the family therapy condition will be maintained post-treatment over time (3 months).

*Hypothesis 3c.* In comparison to the control condition, significantly lower levels of father anxiety in the family therapy condition will be maintained post-treatment over time (3 months).

*Research Question 4*

Do pediatric ALL patients and their parents in the family therapy condition maintain decreased levels of depression across time in comparison to the minimal contact control condition?

*Hypothesis 4a.* Significantly lower levels of depression for patients in the family therapy condition will be maintained post-treatment over time (3 months) in comparison to the control group.

*Hypothesis 4b.* Significantly lower levels of depression for mothers in the family therapy condition will be maintained post-treatment over time (3 months) in comparison to the control group.
Hypothesis 4c. Significantly lower levels of depression for fathers in the family therapy condition will be maintained post-treatment over time (3 months) in comparison to the control group.

Research Question 5

Does patient anxiety decline uniformly across subscales of the RCMAS-2?

Hypothesis 5. In the family treatment group, patients’ levels of physiological anxiety will significantly decrease over time while declines in worry, social anxiety, and defensiveness may not demonstrate significant declines. Levels of anxiety for patients in the minimal contact control condition will either stay the same or increase over time.

Rationale

These hypotheses are supported by the current pediatric chronic illness literature that has established that child patients’ symptoms affect the family (Woodgate & Kristjanson, 1996) and parental distress and patterns of communication affect child distress and psychological adjustment (Dahlquist et al., 2002; Sawyer et al., 1998; Vance & Eiser, 2004).

Method

Participants

Participants will include 150 families with children between the ages of 6 and 17 years old, and who are receiving treatment from the Childhood Cancer & Blood Disorders Program at Dell Children’s Medical Center of Central Texas. Seventy-five of the families will receive family therapy treatment through an ongoing study on family
therapy. Seventy-five of the families will be randomly assigned to a minimal contact control condition and receive treatment as usual. If the SCCIP-ND is found to be a significantly effective intervention, participants in the minimal contact control condition will be offered services after termination of the study. Families will be excluded from the study if their child has an identified emotional or behavioral disorder. Children who are not first time oncology patients and single parent households will also be excluded from the study.

**Instrumentation**

*Demographic Information.* Participants will complete an intake form providing information on their ethnicity, gender, age, and relationship to the pediatric oncology patient.

*Revised Children’s Manifest Anxiety Scale – Second Edition.* The Revised Children’s Manifest Anxiety Scale – Second Edition (RCMAS-2) assesses the degree and nature of anxiety in children from 6 to 19 years old. The scale includes 49 dichotomous items and yields 5 scores: Physiological Anxiety, Worry, Social Anxiety, Defensiveness, and the Inconsistent Responding Index. Psychometric properties of the previous version of this measure have been reported and indicate internal consistency reliability coefficients that range between .76 and .83. Subscale coefficient reliability coefficients range from .56 to .79 and test-retest reliability is adequate. Test-retest reliabilities suggest high reliability over a short (3 week) interval between administrations, with coefficients
ranging from .90 to .98. Additionally, the manual provides adequate validity evidence, supported by several studies (Reynolds, 1985).

*The Children’s Depression Inventory*. The Children’s Depression Inventory (CDI) is the most commonly used rating scale for screening depression in children and adolescents. The 27-item self-report questionnaire is designed for use for children from 7 to 17 years old. The scale has demonstrated adequate reliability (Kovacs, 1992) with internal consistency as measured by coefficient alpha ranging from .71 to .87. Convergent validity is also supported in numerous studies (Asarnow & Carlson, 1985; Reynolds, 1987; Brooks & Kutcher, 2001).

*Beck Anxiety Inventory*. The Beck Anxiety Inventory (BAI) is designed to measure severity of anxiety in individuals 17 and older and has been shown to adequately differentiate anxiety from depression. The scale includes 21 items, each describing a common symptom of anxiety. Respondents are asked to rate how much they have been bothered by each symptom over the past week; a 4-point Likert scale ranging from 0 to 3 is utilized. Intensity of anxiety is classified as minimal, mild, moderate or severe based on the total score that is generated. Extensive methodological testing has established the reliability and validity of this measure (Beck et al., 1988; Fydrich, Dowdall, & Chambless, 1990; Dent & Salkovskis, 1986). Adequate validity is reported and internal consistency reliability coefficients range between .85 and .94 and test-retest reliability data show a coefficient of .75 over one week (Beck, 1993).

*The Beck Depression Inventory*. The Beck Depression Inventory (BDI) is an instrument used The Beck Depression Inventory-II (BDI-II) is one of the most widely
used measures of severity of depression designed for individuals 13 and over. The scale includes 21 items, each describing a common symptom of depression. Respondents are asked to rate how much they have been bothered by each symptom over the past two weeks; a 4-point Likert scale ranging from 0 to 3 is utilized. Depression severity is classified as minimal, mild, moderate or severe based on the obtained total score. Adequate validity is reported and reliability estimates range between .90 and .92; test-retest reliability data show a coefficient of .93 over one week (Beck, 1996).

Procedure

Approval by Human Subjects Committee. This study will comply with the ethical issues and standards of research set forth by the American Psychological Association and the University of Texas at Austin. Before the study, research materials will be submitted for approval to the Departmental Review Committee within the Department of Educational Psychology and the Institutional Review Board of the University of Texas. After the investigation, if found effective, families in the treatment as usual group will be offered family therapy services.

Approval by Dell Children’s Medical Center of Texas. A proposal will be written and presented to Dell Children’s Medical Center of Central Texas. Upon approval, the primary investigator will meet with physicians, nurses, and hospital staff to present the study.
Recruitment of Participants. Participants will be identified through typical intake procedures at Dell Children’s Hospital and will be contacted upon diagnosis. A letter describing the purpose and nature of the study and a consent form will be obtained from each family. The family will bring the signed consent form to the hospital and it will be returned to the principal investigator.

Data Collection. After informed consents are received, a screening process takes place in order to identify qualifying families. During the screening, all children whose parents have given informed consent to participate will be given their own assent form to sign indicating that they agree to participate. Within one week of cancer diagnosis, the patients and their families will be asked to complete the RCMAS-2, CDI, BAI, and BDI-II for the study. The families will be randomly assigned to treatment groups: family therapy or treatment as usual in a minimal contact control condition. Completion of all measures will take approximately 30 minutes. Post-testing will be conducted using the same measures after the intervention. If the family therapy is found significantly effective, participants in the minimal contact control condition will be invited to receive the treatment after study termination.

Power Analysis. A power analysis was conducted using GPower version 3.0.10 to determine the appropriate number of participants that would need to be included within the investigation. It was determined that a sample size of 142 families would achieve a 95% power using an F-test with a significance level of alpha of 0.05 and an effect size of 0.25. The effect size of 0.25 is a best guess estimate, based on previous research and meta-analyses.
Data Analyses and Expected Results

The purpose of this study is to examine the effect of family therapy on child patient and family anxiety and depression. Research questions will be addressed by analyzing data, including scores on measures of anxiety and depression. Statistical analyses will include two and three-way analyses of variance (ANOVA) and repeated measures multivariate analysis of variance (MANOVA).

Assumptions

Descriptive statistics, outliers, and assumptions will be examined prior to conducting the formal analyses and all conditions are expected to be satisfactory. A case summary of outliers will be initially conducted to identify possible outliers in order to run the analysis of variance without any outlying cases. Specifically, standardized residuals provided by SPSS will be inspected and any with absolute values larger than 2.5 will be considered outlying values. If outliers are found, a case analysis will be performed to analyze whether the values change the results and determine whether they should be discarded. The multivariate normality assumption will be analyzed using histograms, descriptive statistics, and the Kolmogorov-Smirnov test in SPSS. It is expected that none of the distributions will differ from normality. The independence of observations assumption will be maintained by random assignment and independent testing of participants. Mauchley’s Test of Sphericity and Levene’s Test of Equality of Error Variances will be used to examine the sphericity and between-groups equality of variance assumptions. No violations are anticipated. Finally, a three-way ANOVA will be conducted to examine potential differences at baseline utilizing demographic data. No
differences on ethnicity, age, or gender are anticipated; if significant differences are observed, the identified variable will be added to subsequent analyses.

**Expected Results**

Three two-way ANOVA will be run on anxiety scores from the RCMAS-2 and BAI to address research question 1: is family therapy effective in reducing levels of anxiety in pediatric oncology patients and their parents? Three two-way ANOVA will be run on depression scores from the CDI and BDI to address research question 2: is family therapy effective in reducing levels of depression in pediatric oncology patients and their parents? Three two-way ANOVA with repeated measures on time will be run on anxiety scores to address research question 3: do patients and their parents in the family therapy condition maintain decreased anxiety across time? Three two-way ANOVA with repeated measures on time will be run on depression scores to address research question 4: do patients and their parents in the family therapy condition maintain decreased depression across time? A repeated measures MANOVA will be run on subscale scores from the RCMAS-2 to address research question 5: does patient anxiety decline uniformly across subscales of the RCMAS-2?

All ANOVA analyses are expected to illustrate significant main effects of both time and group (family therapy vs. control). Of primary interest, however, will be the anticipated significant interaction effect of time and group. If a significant interaction is found, post hoc comparisons using the Bonferroni adjustment will be run and are expected to indicate that levels of both anxiety and depression will decline significantly across time for patients and parents in the family therapy group but remain fairly constant.
for participants in the minimal contact control condition. Further, post hoc tests using the Bonferroni adjustment are expected to indicate that participants will have significantly lower levels of anxiety and depression post-intervention (Time 2) than at the time of diagnosis (Time 1) and significantly lower levels of anxiety and depression after three months (Time 3) than at Time 2. Similarly, the MANOVA analysis is expected to illustrate significant group differences on the multivariate anxiety subscales and a significant interaction effect of time and group. Follow-up tests are expected to indicate that patients in the family therapy condition show a significant decrease only in physiological anxiety across time.

**Summary and Limitations**

The empirically based treatment literature on family therapy and its applicability to psychiatric symptoms suggests that it may be an effective intervention in mitigating symptoms of anxiety and depression in pediatric oncology patients and their families. It is important to consider the limitations of this study in light of the potential findings and implications. One limitation is that the diversity of this study may only be representative of a select children’s hospital in Central Texas. Further, this paper proposes to explore the efficacy of family therapy on anxiety and as measured by self-report questionnaires (RCMAS-2, BAI, CDI, BDI) following diagnosis. Participation in a research study and having to complete questionnaires may quite simply result in increased anxiety in and of itself. Additionally, the use of self-report measures only assesses the severity of subjective reports of anxiety and depression, and may not be the most accurate gauge of
symptoms. Diagnosis is a vulnerable time for families and it may be beneficial for future researchers to seek alternative ways of measuring anxiety in particular (e.g., salivary hormone measures). Finally, Hierarchical Linear Modeling is a more appropriate statistical analysis for this design but is beyond the current educational level of the principal investigator. Despite these limitations, this study contributes to the existing, yet limited knowledge base of the experience of childhood cancer diagnosis on patients and their families.

Directions for Future Research

It is widely accepted that cancer affects the entire family system; however, mechanisms through which psychological treatment effects are gained are not well understood. Contextual investigation of the experiences of individual family members and identification of specific pathways to adaptive change in the family may shed light on this issue. Finally, exploration of how diagnosis impacts broader systems of the child’s life, such as school or socialization, may provide extended support to the family structure.
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