




Measuring the Effects of an Animal-Assisted Intervention for Pediatric Oncology Patients and Their Parents: A Multisite Randomized Controlled Trial

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Amy McCullough, PhD¹ , Ashleigh Ruehrdanz, MPH¹, Molly A. Jenkins, MSW¹, Mary Jo Gilmer, PhD, RN-BC, FAAN^{2,3,4}, Janice Olson, MD⁵, Anjali Pawar, MD⁶, Leslie Holley, MS, CCLS⁷, Shirley Sierra-Rivera, BSN, RN⁷, Deborah E. Linder, DVM, MS, DACVN⁸, Danielle Pichette, CCRP⁹, Neil J. Grossman, MD¹⁰, Cynthia Hellman, MSW¹, Noémi A. Guérin, MS¹¹, and Marguerite E. O'Haire, PhD¹¹

Abstract

Objective: This multicenter, parallel-group, randomized trial examined the effects of an animal-assisted intervention on the stress, anxiety, and health-related quality of life for children diagnosed with cancer and their parents. **Method:** Newly diagnosed patients, aged 3 to 17 years ($n = 106$), were randomized to receive either standard care plus regular visits from a therapy dog (intervention group), or standard care only (control group). Data were collected at set points over 4 months of the child's treatment. Measures included the State-Trait Anxiety Inventory™, Pediatric Quality of Life Inventory, Pediatric Inventory for Parents, and child blood pressure and heart rate. All instruments were completed by the child and/or his/her parent(s). **Results:** Children in both groups experienced a significant reduction in state anxiety ($P < .001$). Parents in the intervention group showed significantly decreased parenting stress ($P = .008$), with no changes in stress among parents in the control group. However, no significant differences between groups over time on any measures were observed. **Conclusions:** Animal-assisted interventions may provide certain benefits for parents and families during the initial stages of pediatric cancer treatment.

Keywords

pediatric oncology, stress, health-related quality of life, parent, animal-assisted intervention

Introduction

In 2017, nearly 10 500 children younger than 14 years are expected to receive a new cancer diagnosis in the United States (American Cancer Society, 2017). While mortality rates have decreased over the past 3 decades, more than 40 000 children continue to undergo cancer treatment each year, which often necessitates invasive and intensive procedures such as venipuncture, port access, surgery, and chemotherapy (Children's Oncology Group, 2016). Moreover, the experiences of receiving a diagnosis of cancer and the treatment that follows present notable psychosocial challenges to the child and family, both at once and over the long-term (Norberg, Poder, & von Essen, 2011).

Receiving a cancer diagnosis creates considerable uncertainty, and affects nearly every aspect of a child's life. Documented sources of child distress include worry

about their disease trajectory and prognosis; limited opportunities to engage with friends, and/or partake in

¹American Humane, Washington, DC, USA

²Vanderbilt University School of Nursing, Nashville, TN, USA

³Monroe Carell Jr. Children's Hospital at Vanderbilt, Nashville, TN, USA

⁴Pediatric Palliative Care Research Team, Nashville, TN, USA

⁵Randall Children's Hospital at Legacy Emanuel, Portland, OR, USA

⁶UC Davis Comprehensive Cancer Center, Sacramento, CA, USA

⁷St. Joseph's Children's Hospital, Tampa, FL, USA

⁸Cummings School of Veterinary Medicine at Tufts University, North Grafton, MA, USA

⁹University of Massachusetts Medical School, Worcester, MA, USA

¹⁰UMass Memorial Children's Medical Center, Worcester, MA, USA

¹¹Purdue University, West Lafayette, IN, USA

Corresponding Author:

Amy McCullough, National Director, Research & Military Affairs, American Humane/1400 16th Street NW, Suite 360, Washington, DC 20036, USA.

Email: amym@americanhumane.org

their favorite interests and school activities; increased time spent in unfamiliar clinical environments; changes in their appearance and abilities; and physical challenges of their diagnosis and treatment procedures, including pain, nausea, and fatigue (Dupuis et al., 2010; Hedstrom, Ljungman, & von Essen, 2005). Behavioral adjustment problems such as anxiety, somatization, and withdrawal, may also occur in children receiving cancer treatment (Moore et al., 2003). These factors have the potential for negatively affecting the child's adjustment to their illness and their overall quality of life (QoL), particularly in the initial postdiagnosis stage when anxiety is typically heightened (Gerali et al., 2011; Myers et al., 2014; Sung et al., 2011).

Sung et al. (2011) found that children receiving treatment for acute lymphoblastic leukemia (ALL) had lower overall, physical, and psychosocial QoL than their healthy peers across all stages of treatment, as rated by their parents via the Pediatric Quality of Life Inventory™ (PedsQL™) Generic (4.0) and Cancer (3.0) modules. However, it is important to note that there is a range of outcomes for this population, and that some children with cancer do not differ significantly from their healthy peers psychologically (Eiser, Hill, & Vance, 2000).

Childhood cancer is an illness that affects not only patients, but their entire family as well (Alderfer & Kazak, 2006). Parents may struggle with distress, depression, and grief to an even greater degree than their child who may not be able to fully grasp the situation due to age or developmental level, or who is likely not burdened with additional economic and family stressors that often accompany diagnosis and daily life (Al-Gamal & Long, 2010; Enskar, Carlsson, Golsater, Hamrin, & Kreuger, 1997). Several studies have identified stress and anxiety as foremost parental reactions to their child's cancer diagnosis, particularly among mothers who often serve as primary caregivers (Gerhardt et al., 2007; Pai et al., 2007; Patino-Fernandez et al., 2008; Piersol, Johnson, Wetsel, Holtzer, & Walker, 2008). Parents' ability to adapt and cope effectively with stress throughout the treatment process can have broader effects on their family relationships and functioning; adjustment and QoL for their children, both sick and well; and their own long-term physical and mental health (Fedele et al., 2013; Ljungman et al., 2014; Rosenberg et al., 2014).

Several studies have found stress and maladaptive adjustment among parents and their children to be largely well-correlated, both during and after cancer treatment (Jalmsell, Kreicbergs, Onelov, Steineck, & Henter, 2010; Okado, Long, & Phipps, 2014; Rodriguez et al., 2012). Likewise, increased stress in parents—as measured by the Pediatric Inventory for Parents (PIP)—has been found to be significantly associated with worsened outcomes of family functioning (Streisand, Kazak, & Tercyak, 2003),

which, in turn, may be related to poor child adjustment (Van Schoors et al., 2017). In contrast, other research highlights great resilience among families, especially as treatment progresses and they grow accustomed to the “new normal” way of life (Gerhardt et al., 2007; Van Schoors, Caes, Verhofstadt, Goubert, & Alderfer, 2015; Wakefield, McLoone, Butow, Lenthen, & Cohn, 2011). Adolescent survivors and their parents have even reported indicators of posttraumatic growth after successful treatment, as measured by increased patience, appreciation of what is most important in life, “positive changes in self, relationships with others, and plans for the future” (Barakat, Alderfer, & Kazak, 2006, p. 417). The degree of family resilience, again, often depends on the progression of parental optimism and parental cumulative stress (Rosenberg et al., 2014), as well as such socially supportive and normalizing factors as family, friends, school, and hospital staff (Askins & Moore, 2008; Sullivan, Fulmer, & Zigmond, 2001; Sahler et al., 2013; Woodgate, 2006).

Given the psychosocial challenges facing this population, as well as the potential impact of parental stress on family outcomes, many studies have highlighted the need for comprehensive care services designed to continually assess child and parent mental health, and to provide tailored, evidence-based support when needed (Al-Gamal & Long, 2010; Best, Streisand, Catania, & Kazak, 2001; Ljungman et al., 2014; Moore et al., 2003). While limited, research regarding adjunctive, mostly parent-based psychosocial interventions has shown promise in this area (Fedele et al., 2013; Sahler et al., 2013; Wakefield et al., 2016). Recently, individual problem-solving skills training sessions with mothers of children newly diagnosed with cancer over an 8-week period were shown to decrease their anxiety, depression, and posttraumatic stress symptomology, with continued beneficial effects postintervention (Sahler et al., 2013). While these parent outcomes are indeed encouraging, there currently exists scarce evaluation of family-based interventions for this population although recommendations to do so have been proffered given the risk of family-wide distress (Askins & Moore, 2008; Streisand et al., 2003; Van Schoors et al., 2015).

One option that could augment treatment to address the psychosocial needs of families is animal-assisted intervention (AAI), which can be generally defined as the purposeful incorporation of specially trained and qualified animals (most commonly dogs) in services to improve human health (IAHAIO, 2014; Nimer & Lundahl, 2007). AAI is an umbrella term often used to describe both structured therapy sessions with animals designed to meet a person's individualized treatment goals (animal-assisted therapy or AAT), as well as informal, nonstructured activities with animals to provide people with comfort, joy, and enrichment (animal-assisted

activities or AAA) (Pet Partners, 2017). The present study's intervention—regular therapy dog visits with children and their families during the initial period of cancer treatment—represents the latter application, and is typical of AAI practice in today's hospital settings.

To date, promising evidence has suggested that our relationships with animals, namely adopting pets or involving animals as adjuncts in therapeutic interventions via AAI, can provide benefits to a variety of populations, including improvements in mood, stress/anxiety, socialization, companionship, and physical health indicators (Fine, 2015; Nimer & Lundahl, 2007). For children and youth, animals often play a salient role in their cognitive and socioemotional development, and provide supportive outlets for play, compassion, and learning (Melson & Fine, 2010). In the context of pediatric illness, therapy dogs have been shown to distract patients and their families from the pain and worry often associated with treatment (Sobo, Eng, & Kassity-Krich, 2006; Wu, Niedra, Pendergast, & McCrindle, 2002). Likewise, several studies with pediatric patients suggest that having a therapy dog present during treatment makes the hospital feel more "like home," in part because dogs are familiar and reminiscent of the child's normative environment (Bardill & Hutchinson, 1997, Wu et al., 2002). Research in pediatric settings also suggest high-levels of parental receptivity to therapy dog visits, and satisfaction with AAI hospital programming (Bouchard, Landry, Belles-Isles, & Gagnon, 2004; Caprilli & Messeri, 2006; Gagnon et al., 2004; Wu et al., 2002). These improved hospital perceptions may also lead to increased motivation among children to actively participate in treatment (Gagnon et al., 2004; Wu et al., 2002).

Therapy dogs have also been found to significantly decrease pain perception, a major stress and QoL factor, among certain pediatric patient populations (Braun, Stangler, Narveson, & Pettingell, 2009; Chubak et al., 2017; Sobo et al., 2006). Lower pain perception, as well as a more rapid recovery from anesthesia, has also been observed in pediatric patients who were visited by a therapy dog shortly after surgery (Calcaterra et al., 2015).

To date, studies measuring the effects of AAI in pediatric oncology settings (eg, Bouchard et al., 2004; Chubak et al., 2017; Gagnon et al., 2004; Ruehrdanz, Jenkins, & McCullough, 2013) have provided important contributions, such as data indicating the feasibility and practical considerations of AAI implementation and research with this specific population, as well as positive child, parent, and medical staff perceptions of therapy dog visitation. In the most recent study to measure the effects of AAI (Chubak et al., 2017), children with cancer reported feeling less distressed, and having significantly decreased worry, fear, sadness, fatigue and pain, after visiting with a therapy dog in the inpatient ward. However, these existing

investigations remain few and, for the most part, relatively preliminary (ie, small [$N < 30$; 1-2 study sites], descriptive pilot studies, with most lacking a control group or random assignment). Likewise, sound evidence concerning AAI's broad impact on the stress, anxiety, and QoL outcomes for children with cancer and their parents is limited and in need of additional scrutiny if therapy dog programs are to continue expansion and/or gain evidence-based credibility in clinical pediatric settings (Chubak & Hawkes, 2016).

In the present study, we followed children with cancer and their parents who either did or did not receive therapy dog visits during regular treatment sessions to determine the physiological (child blood pressure and heart rate) and psychosocial (child and parent stress and anxiety; child health-related quality of life [HRQoL]) effects of AAI for this population. To our knowledge, this research is unique in that it employed a randomized controlled design to measure the impact of a complementary AAI with multiple members of the same family group (children and parents) simultaneously across five hospital settings in the United States. It should be noted that this study also examined the physiological and behavioral effects of sessions on the participating therapy dogs, as their well-being is essential to ethical and effective AAI practice; however, these canine-specific findings are not reported here (see McCullough et al., in press). As such, this article focuses on the child and parent data, and three hypotheses: (1) Patients with childhood cancer who receive AAI will experience less stress/anxiety through the course of the study period than patients who do not receive AAI, (2) patients with childhood cancer who receive AAI will have improved HRQoL when compared to patients who do not receive AAI, and (3) parents of patients with childhood cancer who receive AAI will experience less stress/anxiety through the course of the study period than parents of patients who do not receive AAI.

Method

From January 2013 to July 2013, a feasibility pilot study was conducted at two pediatric hospitals (Ruehrdanz et al., 2013). These efforts led to the current study, which is a multicenter, parallel-group, randomized trial conducted at five pediatric hospitals in the United States. The study protocol was approved by all applicable institutional review boards, institutional animal care and use committees, and scientific review committees prior to data collection.

Participants

Eligible children were newly diagnosed with cancer within the previous 16 weeks, identified by the onsite study coordinator, and screened for eligibility by the study

coordinator and the child's treatment team. Inclusion criteria were (1) children were aged 3 to 17 years and diagnosed with a type of cancer that would require at least monthly outpatient treatments (eg, children with leukemia, lymphoma, solid tumor, or brain tumor) and (2) the primary language of the child and his/her parents was English or Spanish. Families were excluded from the study if the child or his/her parent(s) (1) had a significant cognitive impairment that would preclude them from completing the surveys, even with assistance; (2) had a fear of dogs; and/or (3) had an allergy to dogs. This population reflects a modification to the original protocol utilized in the first year of study. Modifications were made after low enrollment rates and higher than desirable control group dropouts. The modifications included an increased range of patient age (from 3-12 years to 3-17 years), diagnosis (ALL only to any diagnosis that would require at least monthly outpatient treatment) and, for those in the control group, an incentive of a \$100 Visa gift card, distributed at the completion of their study period. The incentive was intended to give those in the control group some benefit and compensation for the time they were investing in completing the forms, and being video recorded. It was anticipated that having the therapy dog visits was enough of a benefit for the intervention group, and so no incentive was provided to this group.

Once the child and parents were screened for eligibility, they were consented/assented by the hospital study coordinator. The study took place at the following sites: Monroe Carell Jr. Children's Hospital at Vanderbilt in Nashville, TN; Randall Children's Hospital in Portland, OR; University of California Davis Children's Hospital in Sacramento, CA; St. Joseph's Children's Hospital in Tampa, FL; and Children's Medical Center at UMass Memorial Health Care, in partnership with Cummings School of Veterinary Medicine at Tufts University, in Worcester/North Grafton, MA.

Interventions

Participants were randomly assigned by the research team using simple randomization procedures (ie, computerized random numbers) to 1 of 2 groups. Both the control and intervention sessions occurred, and data were collected, in private to semiprivate areas in the pediatric hematology/oncology clinic. AAI visits occasionally took place in an inpatient room, depending on site policies and patient health status. All sessions were video recorded to allow researchers to measure therapy dog behavior in the intervention group sessions, as well as establish a similar study environment across groups.

Intervention Group. Participants randomized to the intervention group received regular visits from a registered

therapy dog-handler team authorized to provide AAI onsite, in addition to their standard care offered at the hospital. To support safe interactions, all therapy dog-handlers were required to complete extensive AAI and study training, and therapy dogs had to have passed a behavioral and health evaluation prior to study participation. Therapy dog interactions occurred approximately once per week over 4 months, depending on the child's treatment schedule. Children received visits from the same therapy dog team each week, whenever possible. Sessions were prescribed to last 10 to 20 minutes, with activities documented by the site coordinator and therapy dog-handler. Therapy dog sessions were neither structured nor prescriptive in nature to allow for the therapy dog-handler, child, and family to determine the most appropriate activities based on interests and health status. A list of commonly occurring therapy dog activities was included on the handler-self report form to document AAI session activities.

Control Group. Participants randomized to the control group received standard care at their hospital. Each family received services from the oncology team, which may have included nurses, child life specialists, social workers, and others. Participants in the control group were not prohibited from having interactions with a therapy dog-handler team who happened to be onsite, such as a brief interaction in the waiting room or hallway.

Measures

Demographic and Medical Information. Child and parent participant demographic information was obtained via self-report at baseline (prior to randomization), including the items listed in Table 1. Standard demographic variables were used to describe the sample. Additionally, pet ownership was included as this is a factor that has been thought to influence the impact of AAI. Accuracy of diagnostic information was confirmed by site coordinators and patient medical records.

State-Trait Anxiety Inventory and State-Trait Anxiety Inventory-Child. To measure stress and anxiety in children and parents, the State-Trait Anxiety Inventory (STAI) questionnaire was employed. The STAI is a widely used measure of adult state and trait anxiety (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983) and is considered the "gold standard" for evaluating anxiety (Kain et al., 1997). It contains two 20-item self-report scales, one for trait or inherent anxiety and the other for state or current circumstance-based anxiety. The State-Trait Anxiety Inventory-Child (STAI-CH) was developed for use with children aged 6 to 14 years. Participants who were younger than 6 years had the form verbally administered to them (Spielberger, 1973) by the

Table 1. Demographic Characteristics of the Control and Intervention Groups.

| | Group | | | Group Difference | | | | | |
|--|------------------|---------------------|--------------------------|------------------|----------|------|-------------|-----|-------|
| | All (N = 106) | Control (N = 46) | Intervention (N = 60) | Statistics | | | Dropout | | |
| | | | | t | χ^2 | p | t/ χ^2 | df | P |
| Primary caregivers | 106 | 46 | 60 | | | | | | |
| Secondary caregivers, n (%) | 41 | 15 (32.6) | 26 (43.3) | | | | | | |
| Child age in years, mean (SD) | 8.5 (4.5) | 8.1 (4.6) | 8.9 (4.5) | -0.80 | | 0.43 | -0.104 | 104 | 0.918 |
| Child gender, % (n) | | | | | 0.25 | 0.62 | 0.034 | 1 | 0.853 |
| Male | 53.8 (57) | 56.5 (26) | 51.7 (31) | | | | | | |
| Female | 46.2 (49) | 43.5 (20) | 48.3 (29) | | | | | | |
| Child race, % (n) | | | | | 7.27 | 0.12 | 1.693 | 4 | 0.792 |
| White/Caucasian | 67.9 (72) | 63.0 (29) | 71.7 (43) | | | | | | |
| African American | 7.5 (8) | 8.7 (4) | 6.7 (4) | | | | | | |
| Hispanic/Latino | 14.2 (15) | 13.0 (6) | 15.0 (9) | | | | | | |
| Other | 5.7 (6) | 4.3 (2) | 6.7 (4) | | | | | | |
| Not reported | 4.7 (5) | 10.9 (5) | 0.0 (0) | | | | | | |
| Child diagnosis, % (n) | | | | | | | | | |
| Acute lymphoblastic leukemia (ALL) | 51.9 (55) | 52.2 (24) | 51.7 (31) | | 5.89 | 0.66 | 5.851 | 8 | 0.664 |
| Lymphoma (Burkitt) | 5.7 (6) | 8.7 (4) | 3.3 (2) | | | | | | |
| Lymphoma (Hodgkin) | 6.6 (7) | 6.5 (3) | 6.7 (4) | | | | | | |
| Osteosarcoma | 5.7 (6) | 6.5 (3) | 5.0 (3) | | | | | | |
| Wilms' tumor | 7.5 (8) | 4.3 (2) | 10.0 (6) | | | | | | |
| Neuroblastoma | 1.9 (2) | 4.3 (2) | 0.0 (0) | | | | | | |
| Ewing sarcoma (EWS) | 2.8% (3) | 2.2% (1) | 3.3% (2) | | | | | | |
| Rhabdomyosarcoma | 3.8 (4) | 2.2 (1) | 5.0 (3) | | | | | | |
| Other | 14.2 (15) | 13.0 (6) | 15.0 (9) | | | | | | |
| Time since diagnosis (months), mean (SD) | 1.5 (1.8) | 1.5 (1.9) | 1.6 (1.7) | -0.26 | | 0.79 | 0.059 | 104 | 0.953 |
| Primary caregivers, % (n) | | | | | | | | | |
| Mother | 92.5 (98) | 91.3 (42) | 93.3 (56) | | 0.15 | 0.70 | 0.612 | 1 | 0.434 |
| Father | 37.7 (40) | 34.8 (16) | 40.0 (24) | | 0.30 | 0.58 | 3.621 | 1 | 0.057 |
| Other | 9.4 (10) | 10.9 (5) | 8.3 (5) | | 0.20 | 0.66 | 0.206 | 1 | 0.650 |
| Not reported | 3.8 (4) | 6.5 (3) | 1.7 (1) | | 1.69 | 0.19 | 0.294 | 1 | 0.588 |
| Caregivers attending treatment, % (n) | | | | | | | | | |
| Mother | 97.2 (103) | 97.8 (45) | 96.7 (58) | | 0.13 | 0.72 | 0.218 | 1 | 0.640 |
| Father | 51.9 (55) | 45.7 (21) | 56.7 (34) | | 1.27 | 0.26 | 0.083 | 1 | 0.773 |
| Other | 39.6 (42) | 37.0 (17) | 41.7 (25) | | 0.24 | 0.62 | 0.383 | 1 | 0.536 |
| Parent age in years, % (n) | | | | | 7.90 | 0.10 | 2.806 | 4 | 0.591 |
| 18-25 | 8.5 (9) | 13.0 (6) | 5.0 (3) | | | | | | |
| 26-35 | 39.6 (42) | 30.4 (14) | 46.7 (28) | | | | | | |
| 36-45 | 35.8 (38) | 34.8 (16) | 36.7 (22) | | | | | | |
| ≥46 | 13.2 (14) | 15.2 (7) | 11.7 (7) | | | | | | |
| Not reported | 2.8 (3) | 6.5 (3) | 0.0 (0) | | | | | | |
| Parent race, % (n) | | | | | 3.42 | 0.49 | 1.322 | 4 | 0.858 |
| White/Caucasian | 67 (71) | 65.2 (30) | 68.3 (41) | | | | | | |
| African American | 7.5 (8) | 10.9 (5) | 5.0 (3) | | | | | | |
| Hispanic/Latino | 14.2 (15) | 10.9 (5) | 16.7 (10) | | | | | | |
| Other | 5.7 (6) | 4.3 (2) | 6.7 (4) | | | | | | |
| Not reported | 5.7 (6) | 8.7 (4) | 3.3 (2) | | | | | | |
| Parent marital status, % (n) | | | | | 4.10 | 0.39 | 1.216 | 4 | 0.876 |
| Married | 61.3 (65) | 58.7 (27) | 63.3 (38) | | | | | | |
| Single | 17.9 (19) | 17.4 (8) | 18.3 (11) | | | | | | |

(continued)

Table 1. (continued)

| | Group | | | Group Difference | | | | | |
|-------------------------------|-----------|-----------|--------------|------------------|----------|------|-------------|-----|-------|
| | All | Control | Intervention | Statistics | | | Dropout | | |
| | (N = 106) | (N = 46) | (N = 60) | t | χ^2 | p | t/ χ^2 | df | P |
| Divorced | 9.4 (10) | 6.5 (3) | 11.7 (7) | | | | | | |
| Other | 6.6 (7) | 8.7 (4) | 5.0 (3) | | | | | | |
| Not reported | 4.7 (5) | 8.7 (4) | 1.7 (1) | | | | | | |
| Family income in \$, % (n) | | | | | 7.01 | 0.54 | 6.520 | 8 | 0.589 |
| <10 000 | 8.5 (9) | 8.7 (4) | 8.3 (5) | | | | | | |
| 10 000-14 999 | 7.5 (8) | 10.9 (5) | 5.0 (3) | | | | | | |
| 15 000-24 999 | 15.1 (16) | 19.6 (9) | 11.7 (7) | | | | | | |
| 25 000-34 999 | 12.3 (13) | 6.5 (3) | 16.7 (10) | | | | | | |
| 35 000-49 999 | 8.5 (9) | 10.9 (5) | 6.7 (4) | | | | | | |
| 50 000-74 999 | 15.1 (16) | 17.4 (8) | 13.3 (8) | | | | | | |
| 75 000-99 999 | 8.5 (9) | 6.5 (3) | 10.0 (6) | | | | | | |
| ≥100 000 | 16 (17) | 10.9 (5) | 20.0 (12) | | | | | | |
| Not reported | 8.5 (9) | 8.7 (4) | 8.3 (5) | | | | | | |
| Siblings | | | | | | | | | |
| Have siblings, % (n) | 83 (88) | 82.6 (38) | 83.3 (50) | | 0.01 | 0.92 | 0.039 | 1 | 0.844 |
| Number of siblings, mean (SD) | 1.5 (1.1) | 1.5 (1.2) | 1.5 (1.1) | -0.04 | | 0.97 | -1.284 | 102 | 0.202 |
| Pets | | | | | | | | | |
| Have pets, % (n) | 67 (71) | 63.0 (29) | 70.0 (42) | | 0.57 | 0.45 | 0.328 | 1 | 0.567 |
| Number of pets, mean (SD) | 2.4 (1.5) | 2.6 (1.4) | 2.3 (1.5) | 0.95 | | 0.35 | -0.459 | 69 | 0.648 |
| Dogs, % (n) | 55.7 (59) | 50.0 (23) | 60.0 (36) | | 1.06 | 0.30 | 2.229 | 1 | 0.135 |
| Cats, % (n) | 30.2 (32) | 28.3 (13) | 31.7 (19) | | 0.14 | 0.71 | 0.899 | 1 | 0.343 |
| Fish, % (n) | 6.6 (7) | 8.7 (4) | 5.0 (3) | | 0.58 | 0.45 | 0.717 | 1 | 0.397 |
| Other pets, % (n) | 10.4 (11) | 8.7 (4) | 11.7 (7) | | 0.25 | 0.62 | 0.123 | 1 | 0.726 |

study coordinator, or a parent proxy was used. Children older than 14 years completed the STAI adult forms, unless the site coordinator deemed the child version more suitable.

Pediatric Quality of Life Inventory: General and Cancer Modules. To examine patient quality of life, The Pediatric Quality of Life Inventory (PedsQL™) questionnaire, which is a modular approach to measuring HRQoL in children and adolescents, regardless of health status (Seid, Varni, Rode, & Katz, 1999; Varni, Seid, & Rode, 1999), was employed. The current study utilized both generic core scales and cancer-specific modules. The PedsQL™ 4.0 Generic Core Scale consists of 23 questions that measure the following 4 areas of HRQoL: (1) Physical Functioning, (2) Emotional Functioning, (3) Social Functioning, and (4) School Functioning. Higher scores indicate better HRQoL or fewer problems and/or symptoms. The PedsQL™ Cancer Module 3.0 consists of 27 questions that measure the following 8 areas related to problems specific to children with cancer: (1) Pain and Hurt, (2) Nausea, (3) Procedural Anxiety, (4) Treatment Anxiety, (5) Worry, (6) Cognitive Problems, (7) Perceived Physical Appearance, and (8) Communication. In

accordance with the PedsQL™ Measurement Model, the current study employed the developmentally appropriate forms for all children. Child self-reports were completed by children, ages 5 to 17 years. Parent reports of their child's HRQoL were collected for all children, ages 3 to 17 years.

Pediatric Inventory for Parents. The PIP questionnaire was utilized as a measure of parental stress, and is a 42-item, self-report measure of stress specifically related to caring for a child with a serious illness, such as cancer (Streisand, Braniecki, Tercyak, & Kazak, 2001). The PIP is grouped into 4 subscales: (1) Communication, (2) Emotional Functioning, (3) Medical Care, and (4) Role Function. Parents were asked to rate each item, using a Likert-type scale, for both the frequency and difficulty of that event over the previous week.

All questionnaires were scored per their respective technical manuals.

Blood Pressure and Heart Rate. At the beginning and end of every study session, diastolic and systolic blood pressure and heart rate were obtained onsite as a physiological measure of stress for each child participant. Blood

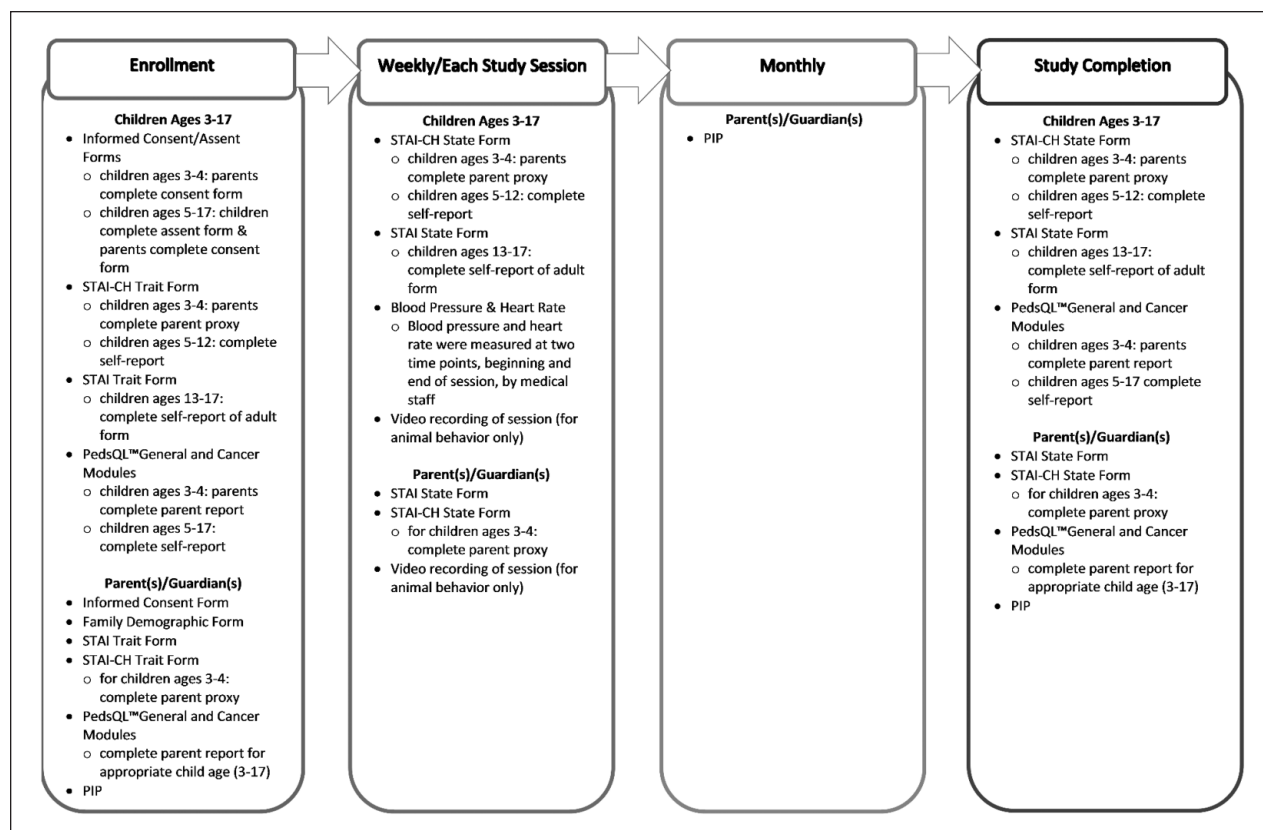


Figure 1. Instrumentation schedule.

pressure and heart rate were obtained from the child while he/she was seated, and were collected once at each time point via either a DynaMap machine or a blood pressure cuff and stethoscope method.

Assessment Schedule. All assessments were prescribed to be collected at baseline and at study end. A subset was also collected at every session (ie, STAI-state, STAI-CH-state, blood pressure, and heart rate) or monthly (ie, PIP). See Figure 1 for a complete instrumentation schedule.

Sample Size, Randomization, and Data Analysis

Sample size was determined via a power analysis, with the STAI-CH serving as the primary outcome, using a small to moderate effect size ($d = 0.40$, power = 0.80, $\alpha = .05$). This yielded a sample size of 50 patients in each group, thus 100 patients were expected to be enrolled. After each patient was screened for eligibility by the hospital, and the child and parent(s) assented/consented to participate, they were randomized to either the control or intervention group.

Data analyses were performed in two phases. First, baseline differences between groups were assessed by

comparing demographic and diagnostic characteristics. The control and intervention groups were compared, as well as completers versus noncompleters. Independent-samples t tests were used for continuous variables and chi-squared tests were used for categorical variables. Second, hierarchical linear modeling (HLM), or linear mixed modeling, was used to examine changes over time in outcome based on condition (Raudenbush & Bryk, 2002). This analysis technique enabled an intent-to-treat analysis without missing data algorithms, as well as an accounting for the nested data design. The levels of the model reflected individuals (level 1), nested within families where multiple parents were respondents (level 2), nested within hospital sites (level 3).

In all models, changes in outcomes were examined over time (number of sessions) as a function of treatment group condition (intervention or control). Time was coded as number of sessions to represent *dose* and to examine differential changes between the intervention and control groups over the course of the program. For measures with multiple assessments after baseline (ie, PIP, STAI, blood pressure, heart rate), time (number of sessions) was mean-centered and both linear and quadratic changes were assessed. For measures with multiple informants (ie, 2 parents), data from both informants

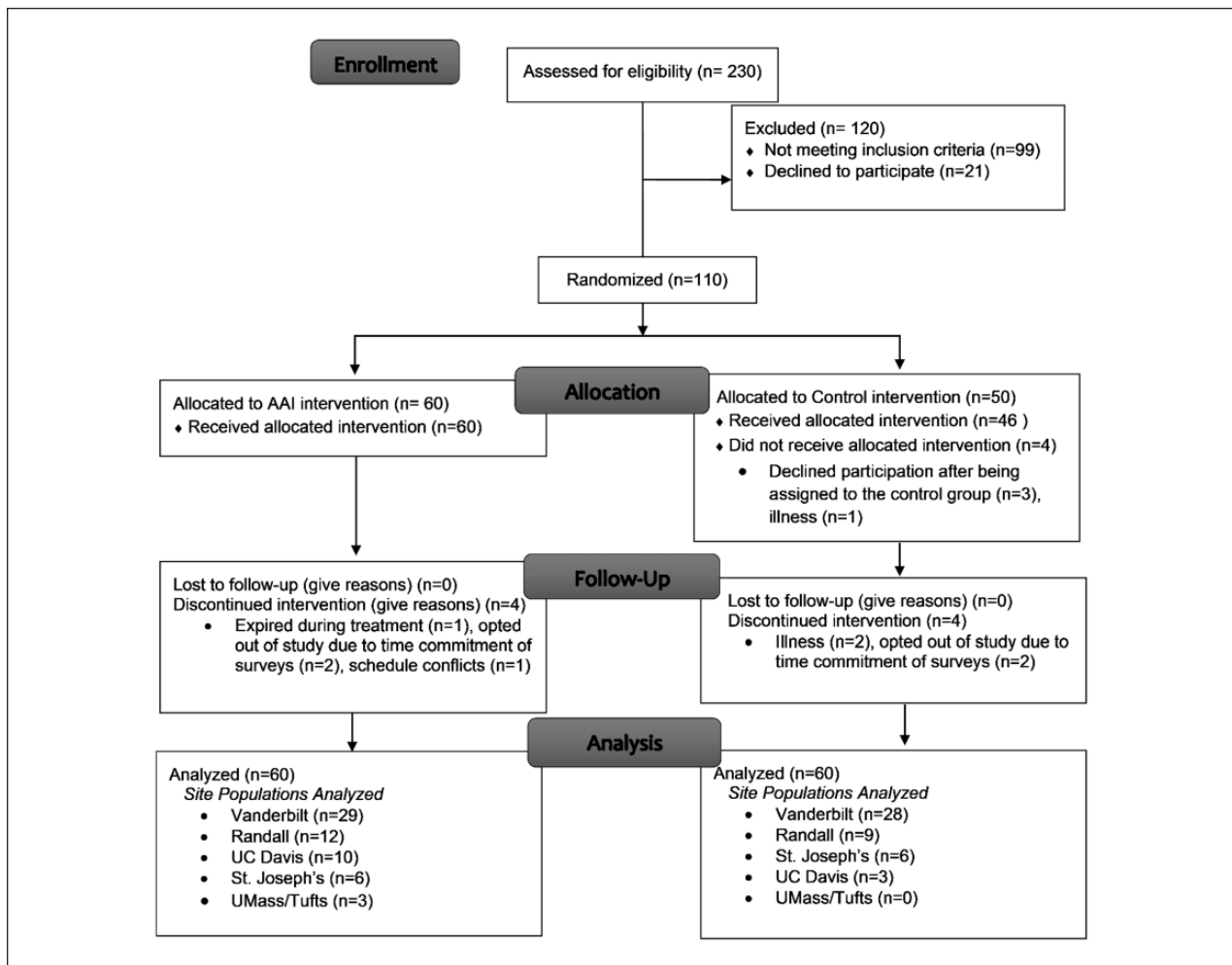


Figure 2. Participant flow diagram.

were included and accounted for with the nested factor of family (Level 2). For survey measures with significant overall outcomes, subscales were also examined. Fixed factors included group (intervention/control), time (dose as number of sessions), group \times time interaction, and the control variables of age, pet ownership, and baseline scores on each measure. For the STAI, the trait score was included as the baseline and the state score was evaluated over time. For physiological measures (blood pressure and heart rate) assessed at postsession, additional control variables included the presession value and time between pre- and postsession samples. Random factors included the individual (level 1), family (level 2), and hospital site (Level 3). The linear mixed model procedure available within the Statistical Package for the Social Sciences Version 24.0 was used. All significance tests were 2-tailed with a significance level of $\alpha < .05$.

Effect size was calculated using Feingold's (2009) formula for treatment efficacy in clinical trials. The group by

time effect sizes were calculated by dividing the model-based estimates of mean differences between the intervention and control group slope difference by the standard deviation of baseline raw scores. For measures with two assessments, the within group effect sizes were calculated as the slope coefficient divided by the within-group baseline raw standard deviation (Feingold, 2013). For measures with multiple assessments, the slope coefficient was multiplied by the mean number of sessions (Feingold, 2013). Effect sizes are reported using Cohen's d , with 0.20, 0.50, and 0.80 indicating small, medium, and large effect sizes, respectively (Cohen, 1992).

Results

Sample Characteristics

Of 230 children screened, 99 did not meet inclusion criteria, 21 declined, 110 consented/assented, and 4 families dropped out prior to data collection (Figure 2). The

primary reasons for ineligibility included: patient was not the appropriate age, a high-risk diagnosis that would not allow for regular participation, an allergy to dogs, and child behavioral problems. While a high-risk diagnosis was not an exclusion criterion, there were some cases in which the severity of disease and subsequent treatment precluded the child from being able to participate in the research study, as determined by their treating physician. Primary reasons for declining the study included a lack of interest in the study, parental concerns about the child's health and ability to participate, and parental worry that the child would not be assigned to the intervention group. The study sample participants included 106 children (46 control, 60 intervention) and 26 therapy dog-handler teams. The average time between diagnosis and study participation was approximately 5 weeks (mean [M] = 1.2 months, standard deviation [SD] = 0.9 months). For all children, the primary caregiver participated in the study. A secondary caregiver also participated for a subset of children, including 32.6% ($N = 15$) in the control group and 43.3% ($N = 26$) in the intervention group. There were no significant differences in demographic characteristics between the control and intervention groups at baseline (Table 1). A total of 7 children/families (6.6%) discontinued the study due to changes in their child's treatment plan, and/or lack of desire to complete surveys. There were no significant differences in demographic characteristics between those who completed the study ($N = 99$) and those who did not complete the study ($N = 7$) on any measure (all P s > .05).

Parents selected their age from given ranges, with the majority indicating they were between the age ranges of 26 and 35 (46.7%) and 36 to 45 (36.7%) and a majority self-identified as Caucasian (67%; Table 1). Most families reported an annual income of less than \$75,000 (67%), had multiple children (83%), and were pet owners (67%). Children ranged in age from 3 to 17 years ($M = 8.5$, $SD = 4.55$). More than half of all diagnoses were ALL (52%, both intervention and control; Table 1). Families were recruited between December 2013 and May 2016, and data were collected between January 2014 and September 2016. There were no adverse events reported by any participant across groups.

A total of 26 therapy dog-handler teams were matched with the intervention group children and families. There were 14 female and 12 male dogs of various ages ($M = 6.3$ years, $SD = 2.7$) and breeds (Labradors and Labrador mixes were most common [$N = 7$]). The teams averaged just under 3 years of therapy dog/AAI experience ($M = 2.9$ years, $SD = 2.3$).

Intervention Sessions

The AAI sessions were nonstructured; the most common activities for children included petting (92% of sessions)

Table 2. Therapy Dog-Handler and Child/Parent Activities during Animal-Assisted Intervention (AAI) Sessions.

| Session Activity | Child, % | Parent, % |
|----------------------------------|----------|-----------|
| Pet the dog | 92 | 55 |
| Talked to the dog | 69 | 48 |
| Viewed dog's photos | 32 | 14 |
| Brushed the dog | 24 | 4 |
| Practiced dog's cues | 22 | 6 |
| Discussed dog breeds, history | 14 | 12 |
| Discussed therapy dogs | 13 | 11 |
| Walked dog | 12 | 2 |
| Took photos of dog | 10 | 16 |
| Played with dog's toy | 9 | 3 |
| Facilitated dog's visit to staff | 5 | 4 |
| Collected dog stickers or beads | 5 | 0 |
| Used lint roller | 4 | 1 |
| Listened to dog's heartbeat | 3 | 1 |
| Taught dog a new trick | 2 | 1 |
| Put bandannas on dog | 2 | 1 |
| Colored picture of the dog | 2 | 0 |
| Drew picture of the dog | 1 | 0 |
| Got water for the dog | 1 | 0 |
| Read to the dog | 1 | 1 |
| Played dog board/card game | 1 | 0 |
| Played game on dog's vest | 1 | 0 |

and talking to (69% of sessions) the dog (see Table 2). A total of 448 AAI sessions were conducted, averaging 24 minutes in length ($SD = 21.1$). The average dose, or number of sessions, per child was 10.2 sessions ($SD = 3.1$).

HLM Random Effects

The 3-level HLMs that were conducted accounted for variance across individuals (level 1), families with multiple respondents per family (level 2), and hospital sites (level 3). Results indicated that the random effects of hospital (intraclass correlation coefficient [ICC] < .202, $P > .272$) and family (ICC < .493, $P > .591$) were not significant in any models. Thus, there was no significant variability in outcomes across families with multiple parents reporting or hospitals. There was significant variability across individuals (ICC range: <.001-.967, P range: <.001-.075) in most models, indicating individual differences in outcomes accounted for by the linear mixed models.

HLM Main Effects

State Trait Anxiety Inventory and State Trait Anxiety Inventory-Child. There were no significant differences in state anxiety changes over time between groups for children ($P = .559$) or parents ($P = .565$; Table 3).

Table 3. Anxiety and Health-Related Quality of Life Outcomes Reported by Children and Parents.

| | Child | | | | | | Parent | | | | | |
|-------------------------------------|--------------|-------------|-----------|-------------|--------------------|-------|--------------|-------------|-----------|-------------|--------------------|-------|
| | Descriptives | | | | Main Outcomes | | Descriptives | | | | Main Outcomes | |
| | Baseline | | Study End | | Change per Session | | Baseline | | Study End | | Change per Session | |
| | N | Mean (SD) | N | Mean (SD) | b | d | N | Mean (SD) | N | Mean (SD) | b | d |
| State-Trait Anxiety Inventory | | | | | | | | | | | | |
| State Anxiety | | | | | | | | | | | | |
| AAI | 47 | 30.6 (7.7) | 52 | 28.8 (6.7) | -0.40*** | -0.50 | 69 | 66.6 (11.3) | 68 | 66.4 (11.4) | 0.43** | 0.38 |
| Control | 40 | 32.4 (8.1) | 40 | 29.3 (5.4) | -0.47*** | -0.59 | 49 | 59.2 (12.8) | 47 | 62.9 (13.7) | 0.53*** | 0.42 |
| Group × Time | | | | | -0.07 | -0.09 | | | | | 0.10 | 0.08 |
| Pediatric Quality of Life Inventory | | | | | | | | | | | | |
| General Quality of Life | | | | | | | | | | | | |
| AAI | 39 | 66.5 (16.9) | 34 | 69.0 (15.6) | -0.08 | -0.05 | 67 | 62.7 (20.7) | 53 | 62.7 (18.9) | 0.10 | 0.05 |
| Control | 31 | 70.0 (18.1) | 27 | 70.4 (22.0) | -0.15 | -0.08 | 48 | 60.0 (19.3) | 38 | 60.3 (23.5) | -0.22 | -0.12 |
| Group × Time | | | | | -0.06 | -0.04 | | | | | -0.33 | -0.16 |
| Cancer Quality of Life | | | | | | | | | | | | |
| AAI | 42 | 68.4 (17.7) | 33 | 70.9 (17.1) | 0.40 | 0.23 | 69 | 64.2 (16.7) | 54 | 65.5 (17.6) | 0.16 | 0.10 |
| Control | 31 | 71.0 (15.2) | 30 | 71.1 (18.2) | -0.12 | -0.08 | 46 | 62.0 (16.5) | 39 | 64.3 (18.3) | 0.05 | 0.03 |
| Group × Time | | | | | -0.52 | -0.32 | | | | | -0.11 | -0.07 |

Abbreviations: N, sample size; SD, standard deviation; b, unstandardized coefficient; d, Cohen's *d* effect size.

* $P < .1$. ** $P < .05$. *** $P < .01$. **** $P < .001$.

Children in both the intervention ($P < .001$) and control ($P < .001$) groups experienced significant reductions in their state anxiety over the course of the study with medium effect sizes. Conversely, parents in both groups experienced significant increases in their state anxiety over the course of the study with small effect sizes ($P < .001$). The internal consistency in this study was medium to high, with Cronbach's α of .507 (state) and .468 (trait) for parent forms, and .750 (state) and .861 (trait) for child forms.

Pediatric Quality of Life Inventory. There were no significant group differences in change over time for health or cancer-related quality of life for children, as indicated by children or parent reports (all P s $> .218$; Table 3). Neither group experienced significant changes in health- or cancer-related quality of life over the course of the study (all P s $> .185$). Cronbach's α of the PedsQL™ Generic Core Scale for this study was .905 for children, and .924 for the parent-proxy reports, while Cronbach's α of the PedsQL™ Cancer Module 3.0 for this study was .926 for children, and .936 for the parent reports.

Pediatric Inventory for Parents. There were no significant group by time differences in overall parenting stress ($P = .212$). However, parents in the intervention group showed significant reductions in overall parenting stress over time ($P = .008$) with a medium effect size, while the control group showed no significant changes over time ($P = .348$; Table 4). There was a significant group by time

interaction effect for communication stress ($P = .020$) with a large effect size. The intervention group showed significant reductions in the frequency of stressful communication events over time ($P = .004$) with a medium effect size, while the control group showed no significant changes over time ($P = .708$). There were no significant group by time interactions for medical care, emotional distress, or role function (all P s $> .070$); however, the intervention group showed significant reductions in the frequency of stressful events related to medical care ($P = .023$) and emotional distress ($P = .002$) with medium effect sizes, while the control group showed no significant changes over time on these domains ($P = .299$ and .559 respectively). Neither the intervention group ($P = .104$) nor the control group ($P = .423$) showed significant changes in stress related to role function over time. The internal consistency in this study was high with Cronbach's α of .951 (frequency), and .959 (difficulty).

Child Blood Pressure and Heart Rate. At pre-session, there was a significant group by time interaction for diastolic blood pressure ($P = .018$), but not for systolic blood pressure ($P = .908$) or heart rate ($P = .584$; Table 5). The control group showed significant increases in diastolic blood pressure at pre-session over the course of the study ($P = .008$), while the intervention group showed no changes over time at pre-session ($P = .627$). At post-session, there were no significant group by time interactions (all P s $> .076$); however, the intervention group showed significant increases over time in systolic blood pressure ($P =$

Table 4. Parent Stress Outcomes.

| Measure | Descriptives | | | | Main Outcomes | |
|---------------------------------|--------------|--------------|-----------|--------------|--------------------|----------|
| | Baseline | | Study End | | Change per Session | |
| | N | Mean (SD) | N | Mean (SD) | <i>b</i> | <i>d</i> |
| Pediatric Inventory for Parents | | | | | | |
| Overall | | | | | | |
| AAI | 71 | 127.1 (28.2) | 60 | 112.0 (31.8) | -1.66** | -0.60 |
| Control | 53 | 129.7 (26.0) | 45 | 111.4 (34.2) | -0.57 | -0.22 |
| Group × Time | | | | | 1.09 | 0.41 |
| Communication | | | | | | |
| AAI | 71 | 24.2 (5.8) | 60 | 21.7 (6.8) | -0.41** | -0.73 |
| Control | 53 | 24.9 (5.6) | 45 | 22.2 (7.2) | 0.05 | 0.09 |
| Group × Time | | | | | 0.47* | 0.84 |
| Medical Care | | | | | | |
| AAI | 71 | 26.9 (6.6) | 60 | 23.5 (7.8) | -0.45* | -0.70 |
| Control | 53 | 26.9 (7.6) | 45 | 22.8 (8.5) | -0.20 | -0.27 |
| Group × Time | | | | | 0.25 | 0.37 |
| Emotional Distress | | | | | | |
| AAI | 71 | 47.9 (12.1) | 60 | 40.7 (13.2) | -0.72** | -0.60 |
| Control | 53 | 49.6 (9.8) | 45 | 40.8 (13.0) | -0.13 | -0.14 |
| Group × Time | | | | | 0.58 ⁺ | 0.53 |
| Role Function | | | | | | |
| AAI | 71 | 27.8 (7.7) | 60 | 24.6 (8.3) | -0.28 ⁺ | -0.37 |
| Control | 53 | 27.7 (7.1) | 45 | 25.2 (8.6) | -0.13 | -0.19 |
| Group × Time | | | | | | |

Abbreviations: AAI, animal-assisted intervention; N, sample size; SD, standard deviation; *b*, unstandardized coefficient; *d*, Cohen's *d* effect size. ⁺*P* < .1. **P* < .05. ***P* < .01. ****P* < .001.

.016), diastolic blood pressure ($P = .027$), and heart rate ($P = .009$) at postsession, while the control group showed no changes over time on any physiological measure at postsession (all P s > .566). With respect to the change from pre- to postsession, there were no significant group by time interactions (all P s > .091); however, the intervention group showed significant increases over time in systolic blood pressure ($P = .021$), diastolic blood pressure ($P = .028$), and heart rate ($P = .017$) from pre- to postsession, while the control group showed no changes over time on any physiological measure from pre- to postsession (all P s > .133).

Discussion

This study sought to determine the effects of regular AAI sessions on the stress and HRQoL for children newly diagnosed with cancer and their parents. Results were mixed, with some significant differences in overall parental stress and anxiety over time in the intervention group when compared with parents who did not receive the AAI. Overall, no significant differences in either stress and anxiety or HRQoL between intervention and control group patients over time were found. Over the study

period, children in both groups experienced less stress and no change in HRQoL, regardless of whether they visited with a therapy dog. However, PIP study data show that certain aspects of stress among parents in the intervention group significantly improved with time, as compared to parents in the control group.

The overall lack of significantly greater improvement among children in the intervention group was unexpected, especially given existing evidence regarding the stress- and QoL-related benefits of human-animal interaction for children (Fine, 2015) and, to a lesser extent, in pediatric hospital environments specifically (Chur-Hansen, McArthur, Winefield, Hanich, & Hazel, 2014; Urbanski & Lazenby, 2012). However, changes across both groups align with existing literature regarding the tendency for stress to ease over the course of treatment for pediatric patients (Gerali et al., 2011; Sawyer, Antoniou, Toogood, Rice, & Baghurst, 2000). Limited significant differences in both stress and HRQoL over time between child study groups may have been due to several factors, such as patient age, diagnosis, and the level of engagement associated with therapy dog activities in intervention group sessions versus control group sessions. Additionally, individual- and family-level

Table 5. Physiological Outcomes in Children (Blood Pressure and Heart Rate).^a

| Measure | Blood Pressure (Systolic) | | | | | | Blood Pressure (Diastolic) | | | | | | Heart Rate | | | | | | |
|-------------------|---------------------------|--------------|--------------------|--------------------|-------------|---------------------|----------------------------|--------------|---------------------|--------------------|--------------|---------------------|--------------|--------------|---------------------|--------------------|--------------|---------------------|-------|
| | Descriptives | | | Change per Session | | | Descriptives | | | Change per Session | | | Descriptives | | | Change per Session | | | |
| | Baseline | Study End | | Baseline | Study End | | Baseline | Study End | | Baseline | Study End | | Baseline | Study End | | Baseline | Study End | | |
| | Mean (SD) | Mean (SD) | b | Mean (SD) | Mean (SD) | b | Mean (SD) | Mean (SD) | b | Mean (SD) | Mean (SD) | b | Mean (SD) | Mean (SD) | b | Mean (SD) | Mean (SD) | b | |
| Preession | | | | | | | | | | | | | | | | | | | |
| AAI | 113.2 (13.0) | 108.3 (11.8) | 0.06 | 65.4 (8.7) | 62.8 (9.2) | -0.02 | 107.0 (24.1) | 95.0 (16.6) | -0.02 | 107.0 (24.1) | 95.0 (16.6) | -0.01 | 107.0 (24.1) | 95.0 (16.6) | -0.01 | 107.0 (24.1) | 95.0 (16.6) | -0.01 | 0.00 |
| Control | 117.2 (15.5) | 108.2 (12.8) | 0.05 | 69.7 (10.4) | 63.5 (9.5) | 0.11 ^{***} | 109.6 (24.9) | 101.2 (17.0) | 0.11 ^{***} | 109.6 (24.9) | 101.2 (17.0) | 0.05 | 109.6 (24.9) | 101.2 (17.0) | 0.05 | 109.6 (24.9) | 101.2 (17.0) | 0.05 | 0.02 |
| Group x Time | | | -0.01 | | | -0.01 | | | 0.13 [*] | | | 0.06 | | | 0.06 | | | 0.06 | 0.03 |
| Postsession | | | | | | | | | | | | | | | | | | | |
| AAI | 114.4 (15.0) | 108.7 (13.4) | 0.09 [*] | 65.6 (8.0) | 65.6 (12.4) | 0.08 [*] | 109.8 (22.9) | 98.4 (19.9) | 0.08 [*] | 109.8 (22.9) | 98.4 (19.9) | 0.14 ^{***} | 109.8 (22.9) | 98.4 (19.9) | 0.14 ^{***} | 109.8 (22.9) | 98.4 (19.9) | 0.14 ^{***} | 0.06 |
| Control | 115.0 (13.6) | 105.8 (15.7) | -0.02 | 67.4 (10.1) | 60.7 (8.4) | -0.02 | 107.5 (18.7) | 103.8 (18.2) | -0.02 | 107.5 (18.7) | 103.8 (18.2) | 0.08 | 107.5 (18.7) | 103.8 (18.2) | 0.08 | 107.5 (18.7) | 103.8 (18.2) | 0.08 | 0.05 |
| Group x Time | | | -0.10 ⁺ | | | -0.07 | | | -0.11 ⁺ | | | -0.05 | | | -0.05 | | | -0.05 | -0.03 |
| Change (pre-post) | | | | | | | | | | | | | | | | | | | |
| AAI | 1.2 (11.2) | .4 (10.8) | 0.08 [*] | .2 (9.0) | 2.8 (11.8) | 0.08 [*] | 2.7 (16.1) | 3.4 (13.7) | 0.08 [*] | 2.7 (16.1) | 3.4 (13.7) | 0.13 [*] | 2.7 (16.1) | 3.4 (13.7) | 0.13 [*] | 2.7 (16.1) | 3.4 (13.7) | 0.13 [*] | 0.08 |
| Control | -2.2 (11.0) | -2.4 (11.3) | -0.01 | -2.4 (7.0) | -2.8 (9.3) | -0.02 | -2.6 (16.5) | 2.6 (13.0) | -0.02 | -2.6 (16.5) | 2.6 (13.0) | 0.10 | -2.6 (16.5) | 2.6 (13.0) | 0.10 | -2.6 (16.5) | 2.6 (13.0) | 0.10 | 0.06 |
| Group x Time | | | -0.09 | | | -0.08 | | | -0.10 ⁺ | | | -0.03 | | | -0.03 | | | -0.03 | -0.02 |

Abbreviation: AAI, animal-assisted intervention; SD, standard deviation; b, unstandardized coefficient; d, Cohen's d effect size.

^aTime is a quadratic variable.⁺P < .1. ^{*}P < .05. ^{**}P < .01. ^{***}P < .001.

resilience factors for which we could not control for, such as the quality and quantity of social support networks among children in both groups, could have contributed to these patient findings (Ritchie, 2001; Woodgate, 2006).

The relatively wide ranges of age and cancer diagnosis represented in our child sample (see Table 1) stem from early efforts to boost participant enrollment. That said, the development and evolution of certain psychological outcomes (ie, stress, QoL, adjustment) for pediatric patients largely depends on their age and type/severity of cancer (Gerali et al., 2011; Sung et al., 2011), so demographic heterogeneity in these areas could have made it difficult to see uniform effects of the AAI in the intervention group. Ideally, adjunctive psychosocial interventions should be designed according to the child's age, diagnosis, and treatment stage given the distinct needs associated with these factors (Askins & Moore, 2008; Gerali et al., 2011). Arguably, younger children could have been more responsive to the AAI than adolescents, who may, for example, prefer to engage in social media rather than in therapy dog visitation. Indeed, some research suggests that participation in animal-related activities tends to decline as children age (Bjerke, Kaltenborn, & Odegardstuen, 2001). Although age was accounted for in our design as a control variable, the study was not powered to evaluate subgroup differences by age. As such, age differences with respect to young people's interest in AAI participation should be a focus of future inquiry, as client receptivity to an intervention may play an important role in its degree of effectiveness.

Additionally, with respect to the physiological effects of AAI sessions, our findings show that children who interacted with a therapy dog had significantly increased blood pressure and heart rate at postsession when compared with the presession measurement over time but that children in the control group experienced no physiological changes from pre- to postsession over their participation in the study. While changes in heart rate and blood pressure were statistically significant, they were not shown to be clinically significant. The elevations in child blood pressure and heart rate throughout the AAI sessions may be attributable to the relatively higher levels of activity (ie, walking the dog and practicing the dog's cues; Table 2) that characterized AAI sessions as compared with control group sessions, and may be indicative of increased engagement rather than stress or simply stress over the course of the program. From our brief observations of videotaped control group sessions, these children mostly spent their time resting and/or quietly interacting with people and entertainment, such as books, TV, and video games.

Future AAI studies with children with cancer may consider alternative physiological measures of stress—such as salivary cortisol and/or hormonal indicators—within

the context of session activity level and intensity. Few AAI studies in pediatric settings have used salivary cortisol as a measure of child physiological stress. In one previous study of hospitalized children with various diagnoses, including cancer (Kaminski, Pellino, & Wish, 2002), reliable analysis of salivary cortisol could not take place due to the evaporation of samples. In another more recent study, which focused on immunocompetent children (ie, those not diagnosed with cancer) undergoing surgery, Calcaterra et al. (2015) found no differences in salivary cortisol responses between the AAI and standard care control group. This study recommended the evaluation of additional physiological stress markers (ie, epinephrine, norepinephrine, endorphin, and oxytocin) in future AAI research.

In contrast to much of the current literature (Ljungman et al., 2014; Van Schoors et al., 2015), parents in both the intervention and control group experienced significantly increased state anxiety over time, as measured by the STAI instrument, with no significant group differences observed. However, the PIP instrument indicated significant overall improvements in stress over time for parents in the intervention group only, with no significant overall changes in parenting stress among control group participants. In fact, parents who received the AAI intervention saw significant improvements over time related to stress and anxiety in almost all areas of the PIP instrument with medium to large effect sizes, including in communication, medical care, and emotional distress (see Table 4); conversely, there were no significant changes on any PIP subscale for parents in the control group.

The area of parental stress most affected by the AAI intervention was communication, with significant difference between study groups with a large effect size. The PIP communication subscale measures the level of stress involved in talking to the doctor and hospital staff, arguing with family members, and speaking with the child about his or her illness (Streisand et al., 2001). This finding suggests that the therapy dog may have served as a social catalyst or facilitator during and/or outside of sessions (McNicholas & Collis, 2006) and, through relaxed or engaged conversation, may have allowed parents to communicate more openly with one another, the staff, and their child about the disease and treatment process. Many scholars have noted both social support and attachment theories as foundations of healing in human–animal relationships (Beck & Madresh, 2008; Kruger, Trachtenberg, & Serpell, 2004), particularly our unique and well-established connections with dogs (Payne, Bennett, & McGreevy, 2015; Prato-Previde, Custance, Spiezio, & Sabatini, 2003). Animals are known to provide direct support via affection and comfort perceived to be without condition or judgment (Kruger & Serpell, 2010), and indirect support via their ability to facilitate

social connections between people (McNicholas & Collis, 2006; O'Haire, McKenzie, Beck, & Slaughter, 2013; Wood et al., 2015).

Improvements in family communication and cohesion have implications for enhanced family functioning and child adjustment postdiagnosis, both of which may serve to buffer cancer-related stress for parents, patients, and the family (Piersol et al., 2008; Van Schoors et al., 2017). Likewise, Adduci et al. (2012) found that when parents communicated with their child effectively about their illness, psychological adjustment outcomes for the child improved. It has also been suggested that clear and sincere communication between parents and medical staff can improve the quality of treatment and care the child receives (Perricone, Polizzi, Morales, Marino, & Scacco, 2012; Tremolada et al., 2010), which could further aid the child's overall cancer experience and recovery.

Notably, parents in the intervention group also experienced a significant reduction in the frequency of emotional distress and stressful events related to their child's medical care over time, as measured by the PIP instrument. These important findings may point to the capacity of therapy dogs to provide parents with social support, comfort, and helpful distraction from treatment, whether through the parents' connecting directly with the therapy dog-handler team, witnessing their child's interactions with the team, talking with staff and family members about the dog, their child's care or related topics, and/or a combination of the three (McNicholas & Collis, 2006; Wu et al., 2002). Given that parental emotional distress often influences the adjustment and well-being outcomes of their child with cancer (and vice versa), these benefits for parents could have broad child- and family-related implications as well (Colletti et al., 2008; Fedele et al., 2013; Jalmsell et al., 2010).

There were several limitations of this study, including hospital site differences (ie, size, patient recruitment capacity, AAI experience); the primary use of self-report data, including the use of the STAI-CH out of the normed range; the potential for survey fatigue; sample size; and the lack of standardized or applicable human-animal interaction measures. Although our sample size was sufficient for a moderate effect size in a homogeneous group, and large as compared with similar research inquiries (Chur-Hansen et al., 2014; Urbanski & Lazenby, 2012), noted positive trends toward significance (see Tables 3-5) indicate that we may have seen additional significant differences between the 2 groups over time had there been slightly more statistical power, participants enrolled, and sessions conducted.

At the time of study design, the STAI-CH served as the primary outcome and was used in conducting the power analysis. One of the unanticipated consequences of expanding the enrollment age range (due to low

enrollment rates) was the need to utilize the STAI-CH outside of its intended age range (ie, 6-14 years of age). Site coordinators and parents helped the younger patients to complete the measure, which may have had unintended consequences regarding the reliability and validity of the nonsignificant findings.

Because of differences in staff resources, there were also certain methodological deviations from the design protocol across sites, including the timing and collection of child blood pressure and heart rate, as well as baseline measurements (ie, some were collected at baseline, while others were collected during the first study session). Also, we did not collect any data on potential covariates, such as underlying mental health histories or concurrent psychological interventions, as we aimed to measure an increasingly common complementary therapy option as it readily occurs in these settings. As such, it should be cautioned that some children may have received additional support or had other co-morbidities that we were unable to factor into our analyses, or control for. Additionally, due to logistical and ethical reasons, patients in the control group were still able to interact with therapy dogs in the hospital if they encountered them in common areas. This design aspect may have contributed to the lack of significant differences between children in the intervention and control groups, especially if these chance encounters were frequent in nature.

Furthermore, we acknowledge that it is challenging to determine the impact of the therapy dog-handler in these types of interactions, although they undoubtedly play an important role in shaping both human and canine outcomes. This may be particularly true for parents/adults, who often interact with handlers more frequently or with greater interest than do their children. Finally, to ensure an ecologically valid presentation of AAI, there was not a structured set of activities or a treatment fidelity checklist used in this study. Instead, the frequency of naturally occurring session activities was tracked and reported. The use of a prescribed intervention protocol should be an area of further AAI inquiry and, if effective, replication in future practice.

However, this study does provide supportive evidence for the use of AAI as an adjunctive treatment modality to address certain stress and anxiety needs of this population, primarily with regard to parent and family outcomes. As the first and largest known randomized controlled trial to rigorously measure AAI's impact on the psychosocial outcomes of children and parents faced with the stress of childhood cancer, several study implications for the fields of AAI and pediatric oncology exist. From a feasibility perspective, this study reinforces existing research (Caprilli & Messeri, 2006; Chubak et al., 2017) by demonstrating that, with comprehensive health and safety protocols in place to safeguard both human and canine

participants, AAI can be successfully incorporated into pediatric treatment without noted harmful effects. Additionally, significant improvements in parental stress and anxiety, namely communication and emotional distress, may positively affect the child with cancer, as well as family functioning and adjustment generally, and could even lend support to the use of AAI as a family-based psychosocial intervention for this population—a largely unique finding in the current AAI literature. Family effects (for patients, parents, and siblings), as well as AAI applications for other pediatric diagnoses, should be explored fully in future research, especially given the relative accessibility and affordability of current AAI services.

As there were significant improvements in stress among parents who received this study's AAI, therapy dogs in hospitals may provide important benefits for parents, and potentially families, of children with pediatric cancer during the initial stages of treatment. Further investigation is essential to confirm and build on these findings to maximize efficient and effective protocols for AAI applications in hospital settings.

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ORCID iD

Amy McCullough  <http://orcid.org/0000-0002-9659-2383>

References

- Adduci, A., Jankovic, M., Strazzer, S., Massimino, M., Clerici, C., & Poggi, G. (2012). Parent-child communication and psychological adjustment in children with a brain tumor. *Pediatric Blood & Cancer*, *59*, 290-294.
- Alderfer, M. A., & Kazak, A. E. (2006). Family issues when a child is on treatment for cancer. In R. T. Brown (Ed.), *Comprehensive handbook of childhood cancer and sickle cell disease: A biopsychosocial approach* (pp. 53-74). New York, NY: Oxford University Press.
- Al-Gamal, E., & Long, T. (2010). Anticipatory grieving among parents living with a child with cancer. *Journal of Advanced Nursing*, *66*, 1980-1990.
- American Cancer Society. (2017). *Cancer facts & figures 2017*. Retrieved from <http://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2017/cancer-facts-and-figures-2017.pdf>
- Askins, M. A., & Moore, B. D. (2008). Psychosocial support of the pediatric cancer patient: Lessons learned over the past 50 years. *Current Oncology Reports*, *10*, 469-476.
- Barakat, L. P., Alderfer, M. A., & Kazak, A. E. (2006). Posttraumatic growth in adolescent survivors of cancer and their mothers and fathers. *Journal of Pediatric Psychology*, *31*, 413-419.
- Bardill, N., & Hutchinson, S. (1997). Animal-assisted therapy with hospitalized adolescents. *Journal of Child and Adolescent Psychiatric Nursing*, *10*(1), 17-24.
- Beck, L., & Madresh, E. A. (2008). Romantic partners and four-legged friends: An extension of attachment theory to relationships with pets. *Anthrozoös*, *21*, 43-56.
- Best, M., Streisand, R., Catania, L., & Kazak, A. E. (2001). Parental distress during pediatric leukemia and post-traumatic stress symptoms (PTSS) after treatment ends. *Journal of Pediatric Psychology*, *26*, 299-307.
- Bjerke, T., Kaltenborn, B. P., & Odegardstuen, T. S. (2001). Animal-related activities and appreciation of animals among children and adolescents. *Anthrozoös*, *14*, 86-94.
- Bouchard, F., Landry, M., Belles-Isles, M., & Gagnon, J. (2004). A magical dream: A pilot project in animal-assisted therapy in pediatric oncology. *Canadian Oncology Nursing Journal*, *14*(1), 14-17.
- Braun, C., Stangler, T., Narveson, J., & Pettingell, S. (2009). Animal-assisted therapy as a pain relief intervention for children. *Complementary Therapies in Clinical Practice*, *15*, 105-109.
- Calcaterra, V., Veggiotti, P., Palestini, C., De Giorgis, V., Raschetti, R., Tumminelli, M., . . . Pelizzo, G. (2015). Post-operative benefits of animal-assisted therapy in pediatric surgery: A randomized study. *PLoS ONE*, *10*(6), e0125813.
- Caprilli, S., & Messeri, A. (2006). Animal-assisted activity at A. Meyer Children's Hospital: A pilot study. *Evidence-Based Complementary and Alternative Medicine*, *3*, 379-383.
- Children's Oncology Group. (2016). *Medical information*. Retrieved from <https://childrensoncologygroup.org/index.php/home/64-medical-information/medical-information>
- Chubak, J., & Hawkes, R. (2016). Animal-assisted activities: Results from a survey of top-ranked pediatric oncology hospitals. *Journal of Pediatric Oncology Nursing*, *33*, 289-296.
- Chubak, J., Hawkes, R., Dudzik, Z., Foose-Foster, J. M., Eaton, L., Johnson, R. H., & Macpherson, C. F. (2017). Pilot study of therapy dog visits for inpatient youth with cancer. *Journal of Pediatric Oncology Nursing*, *34*, 331-341.
- Chur-Hansen, A., McArthur, M., Winefield, H., Hanieh, E., & Hazel, S. (2014). Animal-assisted interventions in children's hospitals: A critical review of the literature. *Anthrozoös*, *27*, 5-18.
- Cohen, J. (1992). A power primer. *Psychological Bulletin*, *112*, 155.

- Colletti, C. J., Wolfe-Christensen, C., Carpentier, M. Y., Page, M. C., McNall-Knapp, R. Y., Meyer, W. H., & Mullins, L. L. (2008). The relationship of parental overprotection, perceived vulnerability, and parenting stress to behavioral, emotional, and social adjustment in children with cancer. *Pediatric Blood & Cancer, 51*, 269-274.
- Dupuis, L. L., Milne-Wren, C., Cassidy, M., Barrera, M., Portwine, C., Johnston, D. L., . . . Sung, L. (2010). Symptom assessment in children receiving cancer therapy: The parents' perspective. *Supportive Care in Cancer, 18*, 281-299.
- Eiser, C., Hill, J. J., & Vance, Y. H. (2000). Examining the psychological consequences of surviving childhood cancer: Systemic review as a research method in pediatric psychology. *Journal of Pediatric Psychology, 25*, 449-460.
- Enskar, K., Carlsson, M., Golsater, M., Hamrin, E., & Kreuger, A. (1997). Parental reports of changes and challenges that result from parenting a child with cancer: An international account. *Journal of Pediatric Oncology Nursing, 14*, 156-163.
- Fedele, D. A., Hullmann, S. E., Chaffin, M., Kenner, C., Fisher, M. J., Kirk, K., . . . Mullins, L. L. (2013). Impact of a parent-based interdisciplinary intervention for mothers on adjustment in children newly diagnosed with cancer. *Journal of Pediatric Psychology, 38*, 531-540.
- Feingold, A. (2009). Effect sizes for growth-modeling analysis for controlled clinical trials in the same metric as for classical analysis. *Psychological Methods, 14*(1), 43-53.
- Feingold, A. (2013). A regression framework for effect size assessments in longitudinal modeling of group differences. *Review of General Psychology, 17*(1), 111-121.
- A. H. Fine, (Ed.). (2015). *Handbook on animal-assisted therapy: Foundations and guidelines for animal-assisted interventions* (4th ed.). San Diego, CA: Elsevier.
- Gagnon, J., Bouchard, F., Landry, M., Belles-Isles, M., Fortier, M., & Fillion, L. (2004). Implementing a hospital-based animal therapy program for children with cancer: A descriptive study. *Canadian Oncology Nursing Journal, 14*, 217-222.
- Gerali, M., Servizoglou, M., Paikopoulou, D., Theodosopoulou, H., Madianos, M., & Vasilatou-Kosmidis, H. (2011). Psychological problems in children with cancer in the initial period of treatment. *Cancer Nursing, 34*, 269-276.
- Gerhardt, C. A., Gutzwiller, J., Huiet, K. A., Fischer, S., Noll, R. B., & Vannatta, K. (2007). Parental adjustment to childhood cancer: A replication study. *Families, Systems, & Health, 25*, 263-275.
- Hedstrom, M., Ljungman, G., & von Essen, L. (2005). Perceptions of distress among adolescents recently diagnosed with cancer. *Journal of Pediatric Hematology/Oncology, 27*(1), 15-22.
- IAHAIO. (2014). *White paper: The IAHAIO definitions for animal assisted intervention and guidelines for wellness of animals involved* (Unpublished report). Retrieved from <http://www.iahaio.org/new/fileuploads/4163IAHAIO%20WHITE%20PAPER-%20FINAL%20-%20NOV%2024-2014.pdf>
- Jalmsell, L., Kreicbergs, U., Onelov, E., Steineck, G., & Henter, J.-I. (2010). Anxiety is contagious: Symptoms of anxiety in the terminally ill child affect long-term psychological well-being in bereaved parents. *Pediatric Blood & Cancer, 54*, 751-757.
- Kain, Z. N., Mayes, L. C., Cicchetti, D. V., Bagnall, A. L., Finley, J. D., & Hofstadter, M. B. (1997). The Yale Preoperative Anxiety Scale: How does it compare with a "gold standard?" *Anesthesia & Analgesia, 85*, 783-788.
- Kaminski, M., Pellino, T., & Wish, J. (2002). Play and pets: The physical and emotional impact of child-life and pet therapy on hospitalized children. *Children's Health Care, 31*, 321-335.
- Kruger, K. A., & Serpell, J. A. (2010). Animal-assisted interventions in mental health: Definitions and theoretical foundations. In A. H. Fine (Ed.), *Handbook on animal-assisted therapy: Theoretical foundations and guidelines for practice* (3rd ed., pp. 33-48). San Diego, CA: Academic Press.
- Kruger, K. A., Trachtenberg, S. W., & Serpell, J. A. (2004, July). *Can animals help humans heal? Animal-assisted interventions in adolescent mental health* (Unpublished report). Center for the Interaction of Animals and Society, University of Pennsylvania School of Veterinary Medicine. Retrieved from <http://www.lemosandcrane.co.uk/dev/resources/Center%20for%20the%20Interaction%20of%20Animals%20and%20Society%20-%20Can%20Animals%20Help%20Humans%20Heal.pdf>
- Ljungman, L., Cernvall, M., Gronqvist, H., Ljotsson, B., Ljungman, G., & von Essen, L. (2014). Long-term positive and negative psychological late effects for parents of childhood cancer survivors: A systemic review. *PLoS One, 9*(7), e103340, 1-15.
- McCullough, A., Jenkins, M.A., Ruehrdanz, A., Gilmer, M.J., Olson, J., Pawar, A., . . . O'Haire, M.E. (in press). Physiological and behavioral effects of animal-assisted interventions for therapy dogs in pediatric oncology settings. *Applied Animal Behaviour Science*.
- McNicholas, J., & Collis, G. (2006). Animals as social supports: Insights for understanding animal-assisted therapy. In A. H. Fine (Ed.), *Handbook on animal-assisted therapy: Theoretical foundations and guidelines for practice* (2nd ed., pp. 49-71). San Diego, CA: Elsevier.
- Melson, G. F., & Fine, A. H. (2010). Animals in the lives of children. In A. H. Fine (Ed.), *Animal-assisted therapy: Theoretical foundations and guidelines for practice* (3rd ed., pp. 223-245). San Diego, CA: Elsevier.
- Moore, I. M., Challinor, J., Pasvogel, A., Matthay, K., Hutter, J., & Kaemingk, K. (2003). Behavioral adjustment of children and adolescents with cancer: Teacher, parent, and self-report. *Oncology Nursing Forum, 30*(5), E84-E91.
- Myers, R. M., Balsamo, L., Lu, X., Devidas, M., Hunger, S. P., Carroll, W. L., . . . Kadan-Lottick, N. S. (2014). A prospective study of anxiety, depression, and behavioral changes in the first year after a diagnosis of childhood acute lymphoblastic leukemia: A report from the Children's Oncology Group. *Cancer, 120*, 1417-1425.
- Nimer, J., & Lundahl, B. (2007). Animal-assisted therapy: A meta-analysis *Anthrozoös, 20*, 225-238.
- Norberg, A. L., Poder, U., & von Essen, L. (2011). Early avoidance of disease- and treatment-related distress predicts post-traumatic stress in parents of children with cancer. *European Journal of Oncology Nursing, 15*, 80-84.
- O'Haire, M. E., McKenzie, S. J., Beck, A. M., & Slaughter, V. (2013). Social behaviors increase in children with autism

- in the presence of animals compared to toys. *PLoS ONE*, 8(2), e57010.
- Okado, Y., Long, A. M., & Phipps, S. (2014). Association between parent and child distress and the moderating effects of life events in families with and without a history of pediatric cancer. *Journal of Pediatric Psychology*, 39, 1049-1060.
- Pai, A. L. H., Greenley, R. N., Lewandowski, A., Drotar, D., Youngstrom, E., & Peterson, C. C. (2007). A meta-analytic review of the influence of pediatric cancer on parent and family functioning. *Journal of Family Psychology*, 21, 407-415.
- Patino-Fernandez, A. M., Pai, A. L. H., Alderfer, M., Hwang, W.-T., Reilly, A., & Kazak, A. E. (2008). Acute stress in parents of children newly diagnosed with cancer. *Pediatric Blood & Cancer*, 50, 289-292.
- Payne, E., Bennett, P. C., & McGreevy, P. D. (2015). Current perspectives on attachment and bonding in the dog-human dyad. *Psychology Research and Behavior Management*, 8, 71-79.
- Perricone, G., Polizzi, C., Morales, M. R., Marino, S., & Scacco, C. F. (2012). Functioning of family system in pediatric oncology during treatment phase. *Pediatric Hematology and Oncology*, 29, 652-662.
- Pet Partners. (2017). *Terminology*. Retrieved from <https://pet-partners.org/learn/terminology/>
- Piersol, L. W., Johnson, A., Wetsel, A., Holtzer, K., & Walker, C. (2008). Decreasing psychological distress during the diagnosis and treatment of pediatric leukemia. *Journal of Pediatric Oncology Nursing*, 25, 323-330.
- Prato-Previde, E., Custance, D. M., Spiezio, C., & Sabatini, F. (2003). Is the dog-human relationship an attachment bond? An observational study using Ainsworth's strange situation. *Behaviour*, 140, 225-254.
- Raudenbush, S. W., & Bryk, A. S. (2002). *Hierarchical linear models: Applications and data analysis methods*. Thousand Oaks, CA: Sage.
- Ritchie, M. A. (2001). Sources of emotional support for adolescents with cancer. *Journal of Pediatric Oncology Nursing*, 18, 105-110.
- Rodriguez, E. M., Dunn, M. J., Zuckerman, T., Vannatta, K., Gerhardt, C. A., & Compas, B. E. (2012). Cancer-related sources of stress for children with cancer and their parents. *Journal of Pediatric Psychology*, 37, 185-197.
- Rosenberg, A. R., Wolfe, J., Bradford, M. C., Shaffer, M. L., Yi-Frazier, J. P., Curtis, J. R., . . . Baker, K. S. (2014). Resilience and psychosocial outcomes in parents of children with cancer. *Pediatric Blood & Cancer*, 61, 552-557.
- Ruehrdanz, A., Jenkins, M. A., & McCullough, A. (2013). *Canines and childhood cancer: Pilot study report* (Unpublished report). Retrieved from <https://www.americanhumane.org/publication/canines-and-childhood-cancer-pilot-study-report/>
- Sahler, O. J. Z., Dolgin, M. J., Phipps, S., Fairclough, D. L., Askins, M. A., Katz, E. R., . . . Butler, R. W. (2013). Specificity of problem-solving skills training in mothers of children newly diagnosed with cancer: Results of a multi-site randomized clinical trial. *Journal of Clinical Oncology*, 31, 1329-1335.
- Sawyer, M., Antoniou, G., Toogood, I., Rice, M., & Baghurst, P. (2000). Childhood cancer: A 4-year prospective study of the psychological adjustment of children and parents. *Journal of Pediatric Hematology/Oncology*, 22, 214-220.
- Seid, M., Varni, J. W., Rode, C. A., & Katz, E. R. (1999). The Pediatric Cancer Quality of Life Inventory: A modular approach to measuring health-related quality of life in children with cancer. *International Journal of Cancer*, 83(Suppl. 12), 71-76.
- Sobo, E. J., Eng, B., & Kassity-Krich, N. (2006). Canine visitation (pet) therapy: Pilot data on decreases in child pain perception. *Journal of Holistic Nursing*, 24, 51-57.
- Spielberger, C. D. (1973). *State-Trait Anxiety Inventory for Children*. Palo Alto, CA: Consulting Psychologist Press.
- Spielberger, C. D., Gorsuch, R. L., Lushene, R., Vagg, P. R., & Jacobs, G. A. (1983). *Manual for the State-Trait Anxiety Inventory*. Palo Alto, CA: Consulting Psychologists Press.
- Streisand, R., Braniecki, S., Tercyak, K. P., & Kazak, A. E. (2001). Childhood illness-related parenting stress: The pediatric inventory for parents. *Journal of Pediatric Psychology*, 26, 155-162.
- Streisand, R., Kazak, A. E., & Tercyak, K. P. (2003). Pediatric-specific parenting stress and family functioning in parents of children treated for cancer. *Children's Health Care*, 32, 245-256.
- Sullivan, N. A., Fulmer, D. L., & Zigmond, N. (2001). School: The normalizing factor for children with childhood leukemia: Perspectives of young survivors and their parents. *Preventing School Failure*, 46(1), 4-13.
- Sung, L., Yanofsky, R., Klaassen, R. J., Dix, D., Pritchard, S., Winick, N., . . . Klassen, A. (2011). Quality of life during active treatment for pediatric acute lymphoblastic leukemia. *International Journal of Cancer*, 128, 1213-1220.
- Tremolada, M., Bonichini, S., GianMarco, A., Pillon, M., Carli, M., & Weisner, T. S. (2010). Parental perceptions of health-related quality of life in children with leukemia in the second week after the diagnosis: A quantitative model. *Supportive Care in Cancer*, 19, 591-598.
- Urbanski, B. L., & Lazenby, M. (2012). Distress among hospitalized pediatric cancer patients modified by pet-therapy intervention to improve quality of life. *Journal of Pediatric Oncology Nursing*, 29, 272-282.
- Van Schoors, M., Caes, L., Knoble, N. B., Goubert, L., Verhofstadt, L. L., & Alderfer, M. A. (2017). Systemic review: Associations between family functioning and child adjustment after pediatric cancer diagnosis: A meta-analysis. *Journal of Pediatric Psychology*, 42(1), 6-18.
- Van Schoors, M., Caes, L., Verhofstadt, L. L., Goubert, L., & Alderfer, M. A. (2015). Systemic review: Family resilience after pediatric cancer diagnosis. *Journal of Pediatric Psychology*, 40, 856-868.
- Varni, J. W., Seid, M., & Rode, C. A. (1999). The PedsQL™: Measurement model for the Pediatric Quality of Life Inventory. *Medical Care*, 37, 126-139.
- Wakefield, C. E., McLoone, J. K., Butow, P., Lenthen, K., & Cohn, R. J. (2011). Parental adjustment to the completion of their child's cancer treatment. *Pediatric Blood & Cancer*, 56, 524-531.

- Wakefield, C. E., Sansom-Daly, U. M., McGill, B. C., Ellis, S. J., Doolan, E. L., Robertson, E. G., Mathur, S., & Cohn, R. J. (2016). Acceptability and feasibility of an e-mental health intervention for parents of childhood cancer survivors: "Cascade." *Supportive Care in Cancer, 24*, 2685-2694.
- Wood, L., Martin, K., Christian, H., Nathan, A., Lauritsen, C., Houghton, S., . . . McCune, S. (2015). The pet factor—Companion animals as a conduit for getting to know people, friendship formation and social support. *PLoS ONE, 10*(4), e0122085.
- Woodgate, R. L. (2006). The importance of being there: Perspectives of social support by adolescents with cancer. *Journal of Pediatric Oncology Nursing, 23*, 122-134.
- Wu, A. S., Niedra, R., Pendergast, L., & McCrindle, B. W. (2002). Acceptability and impact of pet visitation on a pediatric cardiology inpatient unit. *Journal of Pediatric Nursing, 17*, 354-362.

Author Biographies

Amy McCullough, PhD, serves as American Humane's National Director of Research and Military Affairs. Her research responsibilities encompass the design and implementation of rigorous studies to demonstrate the impact of the human-animal bond on both humans and animals. She also promotes animal-assisted therapy nationwide through training and speaking engagements. In 2013, she and her therapy dog were deployed to Boston on behalf of American Humane in the aftermath of the marathon bombings. She is also the owner/handler of Butler, The Weather Channel Therapy Dog. She holds a master's degree from Queens University of Charlotte and a doctoral degree from the University of Denver.

Ashleigh Ruehrdanz, MPH, serves as a program manager for American Humane. Her background includes work in child welfare and human-animal interactions. Her current research and evaluation focus is on demonstrating the effects of animal-assisted interventions for children and those who have experienced trauma through the design and implementation of comprehensive studies and programs. She received her master's degree in public health from the University of Colorado.

Molly A. Jenkins, MSW, serves as research analyst and human-animal interaction specialist for American Humane. Her background includes work in animal health and behavior, child welfare, and human-animal interaction, with a current research focus on the effects of animal-assisted interventions for children and those who have experienced trauma. She received her master's degree in social work from the University of Denver, with certification in animal-assisted social work from the Institute for Human-Animal Connection.

Mary Jo Gilmer, PhD, RN-BC, FAAN, serves as director of the Pediatric Palliative Care Research Team at Vanderbilt University Children's Hospital. Her area of research is to reduce the suffering and morbidity of families affected by cancer and the loss of a child through controlled, longitudinal research on the psychosocial outcomes of these families. Her newest project in the animal-assisted interaction field aims to improve childhood cancer treatment by lending credibility to an adjunctive

treatment modality aimed at providing meaningful comfort of a therapy dog. Her hope is that this research leads to a nursing-driven model of care that will improve long-term psychosocial health through widespread sustainable interventions that lower health care costs. She earned her PhD in nursing at the University of North Carolina at Chapel Hill.

Janice Olson, MD, is the medical director of the Children's Cancer and Blood Disorders at Randall Children's Hospital, a part of Legacy Health System, a community based not-for-profit health care system in the Pacific Northwest. She is a member of COG and ASPHO and is currently serving as the Chair of ASPHO's Practice Committee while bringing up a new Australian Shepherd puppy in her spare time. Randall Children's in Portland is proud to have participated in animal-assisted therapy for more than 20 years.

Anjali Pawar, MD, serves as an associate professor in pediatric hematology oncology at UC Davis Comprehensive Cancer Center in Sacramento, California. She became board certified in pediatric hematology oncology in 2011. Besides the conventional therapy for pediatric malignancies, She has a special interest in healing beyond medicines. She feels strongly that canines and children go together like milk and cereal.

Leslie Holley, MS, CCLS, works at St. Joseph's Children's Hospital in Tampa, FL. She has been a Certified Child Life Specialist (CCLS) for 13 years, with several years of experience with the pediatric oncology patient population. She is research driven, and is currently working on her dissertation for her doctorate in educational leadership.

Shirley Sierra-Rivera, BSN, RN, serves as a pediatric hematology/oncology registered nurse and a research nurse coordinator at St. Joseph's Children's Hospital in Tampa, FL. She has been an RN for 7 years, specializing in the pediatric oncology patient population. She obtained her bachelors of science in nursing from the University of South Florida.

Deborah E. Linder, DVM, MS, DACVN, a board-certified veterinary nutritionist, is a research assistant professor at Cummings School of Veterinary Medicine at Tufts University and associate director of the Tufts Institute for Human-Animal Interaction. She has spoken at national and international conferences, and is an expert in pet obesity, nutrition communication, and in human-animal interaction. Her recent research includes the impact of animal-assisted interventions on childhood obesity and child literacy.

Danielle Pichette, CCRP, started her research career at UMass Medical School in 1994. In 1999, she began working for the Institutional Review Board obtaining her certified IRB professional(CIP) certification. She joined the Pediatric Oncology team as a clinical research coordinator in 2011, and obtained her certified clinical research professional (CCRP) certification in 2016.

Neil J. Grossman, MD, is a pediatric hematologist-oncologist with UMass Memorial Medical Center in Worcester, Massachusetts. He received his medical degree from Boston University School of Medicine, and has been practicing for more than 20 years.

Cynthia Hellman, MSW, serves as research analyst for American Humane. Her background includes incorporating animal-assisted interventions in her work with children, youth, and adults with disabilities and traumatic brain injuries. She received her master's degree in social work from the University of Denver and a certification in animal-assisted social work from the Institute for Human-Animal Connection.

Noémi A. Guérin, MS, obtained a bachelor of science in biology from the University of Rennes, France, and a master's degree in human-animal interaction from Purdue University.

She is currently the behavior coding coordinator at the Center for the Human-Animal Bond at Purdue University.

Marguerite E. O'Haire, PhD, received her BA in psychology from Vassar College (2008) and her PhD in psychology from The University of Queensland (2014). Since then, she has worked as an assistant professor of human-animal interaction in the Center for the Human-Animal Bond, College of Veterinary Medicine, Purdue University. Her research focuses on the unique biopsychosocial effects of interacting with animals for humans, including individuals with autism spectrum disorder and posttraumatic stress disorder.