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# Impact of Animal-Assisted Interaction on Anxiety in Children With Advanced Cancer and Their Caregivers

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## Abstract

**Background:** Pediatric patients with advanced cancer and their caregivers have unique psychosocial needs. Anxiety often worsens throughout treatment for both patients and parents, and, if undertreated, can cause suffering. Animal-assisted interaction (AAI) incorporates animals into patient care in a structured manner for the purpose of therapeutic benefit.

**Objective:** To evaluate feasibility of incorporating AAI into patient care and to assess AAI effectiveness in decreasing patient and caregiver anxiety in pediatric patients with advanced cancer, defined by relapsed or refractory disease.

**Design:** Randomized controlled study.

**Setting/Subjects:** Participants were children ( $n=19$ ) and parents ( $n=21$ ) who were randomized to AAI group or usual care (UC) group.

**Measures:** Participants completed weekly measures to assess anxiety, including the 20-question State-Trait Anxiety Inventory (STAI).

**Results:** Our results demonstrated feasibility of the use of AAI in children with advanced cancer. While they did not reveal a significant difference in anxiety scores over the four sessions in either group, parents randomized to the AAI group had lower STAI State subscores at initial visit in comparison to the UC group. The difference in initial STAI State anxiety scores for caregivers may indicate a positive effect of AAI in reducing anxiety surrounding appointments through anticipation of seeing a therapy dog.

**Conclusion:** Further research is needed to determine the effectiveness of AAI in pediatric patients with advanced cancer and their caregivers, but results are promising that participation in AAI may lessen caregiver anxiety. Clinical Trial Registration Number is: NCT03765099

**Keywords:** animal-assisted interaction; pediatric cancer; pediatric palliative care

## Background

APPROXIMATELY 10,470 CHILDREN in the United States ages 0 to 14 years were diagnosed with cancer in 2022. Of these, 1050 are expected to die related to their disease.<sup>1</sup>

While outcomes for children and adolescents with cancer have improved over the last 50 years, it remains a leading cause of death in the pediatric population. Historically, pediatric cancer research focused on survival rates and treatment-related toxicities. However, with improvement in

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Accepted July 21, 2023.

outcomes, research focus has shifted to include not only evaluation of physical functioning but also, importantly, psychosocial and quality of life measures as well.<sup>2</sup>

Children and adolescents undergoing cancer treatment experience a variety of complex psychosocial symptoms including anxiety, depression, worry, sadness, difficulty with communication, loss of independence, and fear of being alone.<sup>3</sup> These symptoms are exacerbated by limited opportunities to spend time with peers, physical symptoms from chemotherapy treatments, and changes in appearance. Patients with advanced disease, defined in our study as relapsed or refractory cancer, may face a higher burden of stress due to fear and anxiety surrounding prognosis. If untreated, this anxiety can lead to diminished quality of life for both patients and families.<sup>4-6</sup>

Parents of children with advanced cancer diagnoses likewise undergo significant emotional distress due to their child's vulnerability and new limitations to daily living. Tension exists to preserve the parent-child relationship and to communicate effectively with health care providers.<sup>7</sup> Parental distress has been correlated with parents' perception of their child's suffering.<sup>8</sup> Interventions to alleviate patient suffering may decrease parental psychological distress. Mitigation of parental distress may also enhance children's well-being.

Given that children with advanced cancer and their caregivers have unique psychosocial needs, providers should determine effective methods to address these symptoms. Animal-assisted interactions (AAIs) have been shown to help with communication and socialization and alleviate many symptoms including anxiety, pain, and feelings of worry, sadness, or anger.<sup>9,10</sup> Many prior studies have focused on AAI's acute effect on anxiety during hospitalization or surrounding procedures in both oncologic and nononcologic populations and have demonstrated its efficacy.<sup>11,12</sup>

While those data are encouraging, AAI and its effect on anxiety have been less well studied in children with advanced cancer and their caregivers. Silva and Osorio found that AAI improved patient-reported pain and overall stress in children with cancer and showed improvement in caregiver anxiety and mental confusion, characterized by feelings of worry or uncertainty.<sup>13</sup> McCullough et al. conducted a multisite randomized controlled trial in children with newly diagnosed cancer and found similar results in caregivers with decreased stress levels in parents in the AAI intervention compared to a control.<sup>14</sup>

There have been promising studies evaluating AAI's effect on psychosocial symptoms in adult patients with advanced cancers and terminal illness. In a German qualitative study, researchers observed several positive responses in their patients, including promotion of communication and relaxation.<sup>15</sup> Another study of AAI in terminally ill adults found a statistically significant reduction in anxiety, which correlated with prior pet ownership.<sup>16</sup>

This study evaluated the feasibility of conducting AAI in children with advanced cancer and assessed potential benefit for mitigating anxiety in patients with advanced disease and their caregivers.

## Methods

### Enrollment

After Institutional Review Board approval, the research team consulted with each patient's primary oncologist before

approaching the family for consent to ensure there were no barriers to study participation. All patients were receiving cancer treatments at a pediatric hematology/oncology outpatient clinic in the Southeast United States. Informed consent was obtained from the child's caregiver(s) and assent was obtained from child participants. Inclusion criteria for patients were as follows: age between 3 and 17 years, diagnosis of advanced (relapsed or refractory) cancer, and English speaking (to participate in consents, surveys, and AAI). Inclusion criteria for caregivers were caregiver or parent coming to the majority of their child's appointments and English speaking for consents and surveys. If either child or caregiver did not meet inclusion criteria, then the pair was not deemed eligible for study. Children and parents with cognitive impairment or self-reported fear of or allergy to canines were excluded from study enrollment as well. Of 31 child-parent dyads approached from February 2019 to May 2021, 30 (96.8%) agreed to participate, with one family excluded due to caregiver fear of dogs.

### Randomization

Following enrollment, participants were randomly assigned to either the AAI intervention group (AAI group) or usual care group (UC group). Randomization was done using a computer-generated, permuted block program. Those assigned to the AAI group had visits with a therapy dog and its handler during oncology clinic appointments or hospitalizations; those assigned to UC group underwent standard clinic visits. An incentive in the form of a \$10 gift card was added weekly for the UC group, as well as a \$50 gift card after completion of the study as compensation for time invested to complete surveys.

### Procedures

Once randomized, all patients in both groups completed trait measures at baseline and state stress/anxiety measures during each clinic visit for up to 12 weeks. The AAI group participated in up to 12 weekly sessions with a therapy dog and its handler during their clinic appointments or hospitalization. Visits were primarily outpatient (92.5%); however, AAI visits were conducted in the inpatient setting if patients were hospitalized and unable to come to clinic. AAI sessions consisted of ~15 minutes of activities with the dog such as petting the dog, talking to the dog, teaching the dog tricks, or brushing the dog. Sessions were video-recorded. Researchers reviewed 20% of sessions to confirm consistency and fidelity of implementation.

The registered canine and handler received training and certification from the animal-assisted therapy organization, Pet Partners. To become certified, the handler passed a written online test and practical exam. Mandatory handler education included topics such as confidentiality, infection control, and effective communication. Pet Partners requires handler-canine dyads to be re-evaluated every two years to ensure suitability of the animal as it matures. Certified canines must be at least one year old. While there is no specific training, the dog must be deemed extremely obedient, of the right temperament, and welcoming to all.

The registered canine and handler team from our study remained in good standing with their animal-assisted therapy organization. All visits included in analysis were with the same canine and handler dyad.

## Measures

### Demographics

Families completed a 14-item family demographic form detailing age, gender, diagnosis, family members, and pets. Handlers also filled out a nine-item Animal Handler Demographic Form addressing qualifications of canine and handler.

### Anxiety

The State-Trait Anxiety Inventory-Child (STAI-CH) and STAI were used to assess anxiety. The 20-item STAI-CH is a validated scale of anxiety for patients aged 5 to 17 years; the 20-item STAI is validated to assess anxiety in adult participants.<sup>17,18</sup> Specifically, the STAI-CH has been used in multiple childhood cancer studies.<sup>19</sup> Child participants in both the AAI and UC groups completed the STAI-CH Trait subscale at baseline before randomization and the STAI-CH State subscale weekly. AAI group participants completed the State subscale each week after AAI intervention. Caregiver participants in both AAI and UC groups completed the STAI Trait subscale at baseline before randomization and the STAI State subscale weekly during clinic visits. For the AAI group, completion of the State subscale was timed for after each AAI intervention (Table 1). The Trait subscale is intended as a general measure of a subject's tendency to have anxiety during activities of daily living and includes questions that assess general measures of calmness, security, and confidence. The State subscale measures a subject's anxiety at the moment they take the survey and includes questions that assess subjective feelings of apprehension, nervousness, worry, and tension. The possible range of scores on each subscale (State and Trait) from the STAI-CH is 20 to 60, while the possible range from the STAI (adults) is 20 to 80. STAI scores are interpreted as "no or low anxiety" (20–37), "moderate anxiety" (38–44), and "high anxiety" (45–80).<sup>20</sup> Similarly, higher STAI-CH scores indicated higher levels of anxiety.

### Data analysis

For inclusion in data analysis, patients and caregivers must have completed a minimum of four weeks of assessments. Of the initial 30 randomized families, 19 patients and 21 parents met the criteria and were included in the analysis (Fig. 1). Data analyses were conducted using IBM SPSS Statistics (Version 28). Frequency distributions were used to summarize nominal and ordinal categorical variables. Due to the small sample size and skewness, medians, interquartile ranges (IQRs), and range were used for summarizing the continuous age and STAI score distributions. Mann-Whitney and chi-square tests of Independence were conducted to compare the demographic and clinical characteristics of the participants in the two study data analysis groups at baseline. Assessments of the effects of AAI on the State anxiety scores for both children and parents were conducted using generalized linear models that included the respective scores after the first clinic visit as a covariate. Interpretations of statistical significance maintained a maximum alpha of 0.05 ( $p < 0.05$ ).

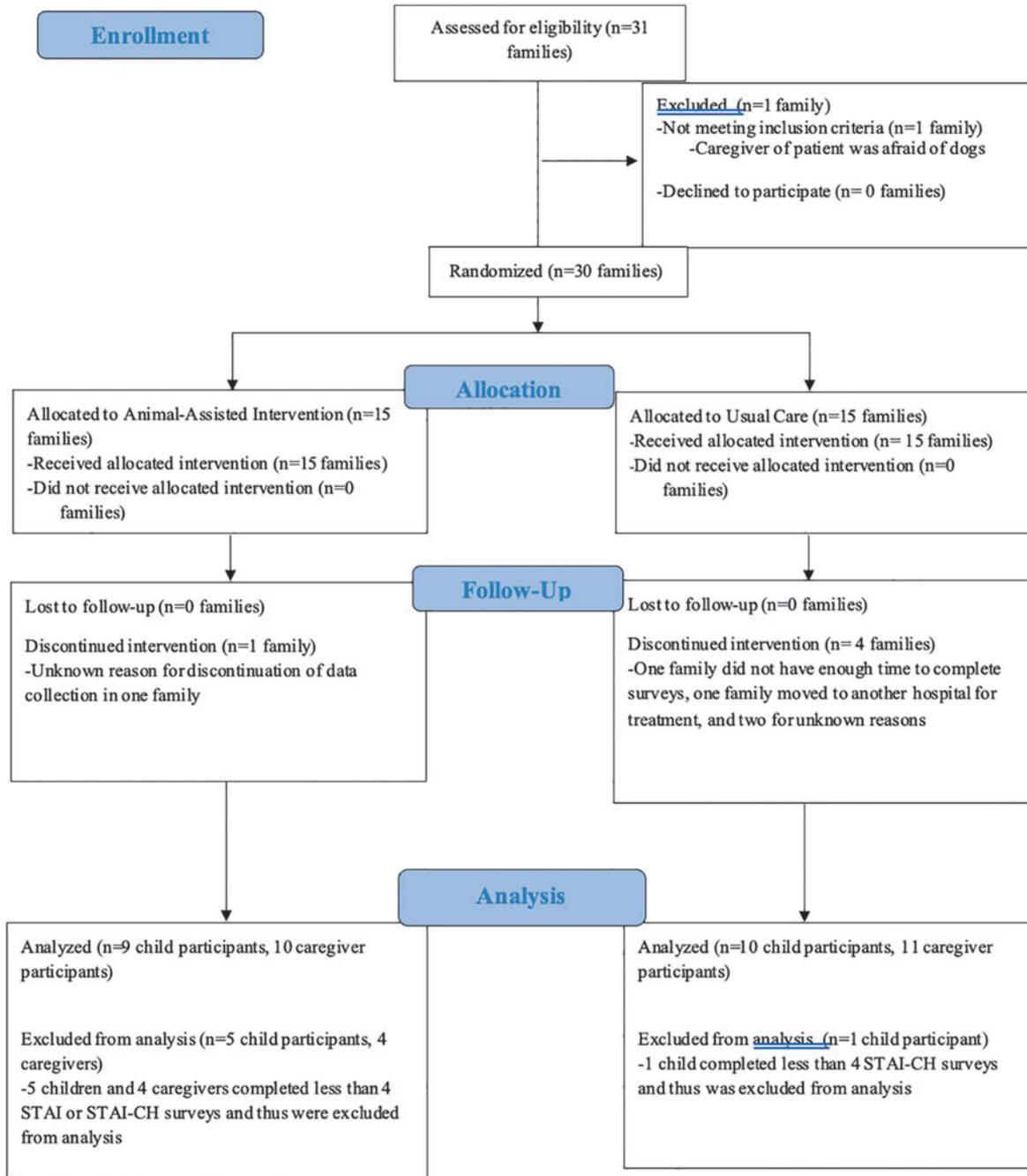
### Results

The 19 children in the analysis sample ranged in age from 5 to 17 years with a median age of 9. Slightly more than half (53%) were female, and approximately two-thirds self-reported as white or Caucasian. The children had a variety of diagnoses, including 6 patients (32%) with leukemia/lymphoma, 10 patients (52%) with solid tumors, and 3 patients (16%) with cranial nervous system (CNS) tumors. Parental participants were mostly mothers (75%) with fathers representing the other 25%. No statistically significant differences between the study groups in any of the characteristics were observed ( $p > 0.20$ ). Trait anxiety scores at baseline were also very similar in both groups for both the children and adults. Both median values tended to be in the lower-to-middle portion of the possible range of scores for their respective measures (children: median = 32; adults: median = 40) (Table 2).

TABLE 1. MEASURES AND SCHEDULE

Variable	Measure	Time	Schedule
AIM 1		Minute	
Safety/feasibility	AAT activity log	5	After AAI
Feasibility	Recruitment rate and attrition		During consent/assent. After final AAI
Intervention	Videotaping of all sessions		During AAI
AIM 2	Child		
Anxiety—Trait	STAIC trait form	5	Baseline
Anxiety—State	STAIC state form	5	Baseline and weekly
Perceptions of AAI	Open-Ended Interview Questions (intervention group only)	15	End of study
	Parent		
Anxiety—Trait	STAI—Trait form (Adult)	5	Baseline
Anxiety—State	STAI—State form (Adult)	5	Baseline and weekly
Perceptions of AAI	Open ended questions (intervention group only) Animal-Handler (intervention group only)	15	End of study
Personal characteristics	Demographic and information form	10	Baseline
Canine assessment	Canine behavioral assessment (CBARQ)	10	Baseline

AAI, animal-assisted interaction; STAIC, State-Trait Anxiety Inventory for Children.



**FIG. 1.** Consort diagram. Thirty-one patients and their caregivers were approached to either receive AAI intervention or UC. One family was excluded due to reported fear of dogs. In the AAI group, one family was lost to follow up for unknown reason. Of the remaining 14 participating families, 9 children and 10 caregivers met analysis criteria with completion of at minimum four STAI surveys. In the UC group, four families were lost to follow up; one due to insufficient time to complete surveys, one due to moving away, and two for unknown reasons. Of the remaining 11 participating families, 10 children and 11 caregivers met analysis criteria with completion of at minimum 4 STAI surveys. AAI, animal-assisted interaction; STAI, State-Trait Anxiety Inventory; UC, usual care.

Summaries of the state anxiety scores for both the child and parental participants are shown in Table 3. No statistically significant difference was observed between the State STAI-CH scores during their first clinic visit (UC) and after their first session with the dog (AAI,  $p=0.621$ ). Median scores for both groups 30 (UC) and 28 (AAI) are in the lower

end of the range of possible scores for that measure (20–60). After controlling for first session scores, no statistically significant difference between the groups was observed in the change in STAI-CH scores from first to fourth session ( $p=0.170$ ). Median change was  $-3$  points for children in the UC group (range:  $-13$  to  $+8$ ) while the median change was  $+1$

TABLE 2. DEMOGRAPHIC CHARACTERISTICS BY STUDY GROUP

	Overall (N=19)	Usual care (N=10)	AAI (N=9)	p
<b>Child with cancer</b>				
	<i>Median (IQR) min, max</i>	<i>Median (IQR) min, max</i>	<i>Median (IQR) min, max</i>	
Age (years)	9 (7, 12) 5, 17	10 (7, 12) 5, 13	8 (5, 12) 5, 17	0.511
STAI trait score	32 (27, 40) 22, 48	30 (27, 41) 22, 46	35 (27, 40) 25, 48	0.596
	n (%)	n (%)	n (%)	
Gender				0.809
Male	9 (47)	5 (50)	4 (44)	
Female	10 (53)	5 (50)	5 (56)	
Race	N=18	N=9		0.343
White/Caucasian	12 (67)	6 (67)	6 (67)	
Black/African American	1 (6)	0 (0.0)	1 (11)	
Other <sup>a</sup>	3 (16)	1 (11)	2 (22)	
Multiple	2 (11)	2 (22)	0 (0)	
Diagnosis group				0.279
Leuk/lymp	6 (32)	2 (20)	4 (45)	
Solid	10 (52)	7 (70)	3 (33)	
CNS	3 (16)	1 (10)	2 (23)	
Family currently has pets				0.845
No	8 (42)	4 (40)	4 (44)	
Yes	11 (58)	6 (60)	5 (56)	
<b>Adult participant</b>				
	Overall (N=21)	Usual care (N=11)	AAI (N=10)	
Relationship to patient	N=20		N=9	0.795
Mother	15 (75)	8 (73)	7 (78)	
Father	5 (25)	3 (27)	2 (22)	
Age group (years)	N=20	N=11	N=9	0.201
18–25	2 (10)	1 (9)	1 (11)	
26–35	8 (40)	5 (46)	3 (33)	
36–45	7 (35)	2 (18)	5 (56)	
46 or older	3 (15)	3 (27)	0 (0)	
Race	N=19	N=11	N=8	0.517
White/Caucasian	13 (69)	8 (73)	5 (63)	
Black/African American	1 (5)	1 (9)	0 (0)	
Hispanic/Latino	1 (5)	0 (0)	1 (12)	
Other <sup>b</sup>	4 (21)	2 (18)	2 (25)	
	<i>Median (IQR) min, max</i> N=18	<i>Median (IQR) min, max</i> N=9	<i>Median (IQR) min, max</i> N=9	
STAI trait score	40 (31, 44) 26, 68	39 (34, 48) 30, 68	40 (30, 43) 26, 56	0.690

<sup>a</sup>Include 1 Asian, 1 Hawaiian, 1 Unknown.

<sup>b</sup>Include 1 Asian, 1 Hawaiian, 2 Unknown.

CNS, central nervous system; IQR, inter-quartile range.

for the children in the AAI group (range: –6 to 19, Fig. 2 and Table 3).

Contrary to the children, there was a statistically significant difference between the first week State anxiety scores for the parents ( $p=0.003$ ). Median parental score at the first clinic visit (UC) was 48 (IQR=34, 59), while the median

score just after the first session with the dog for the parents in the AAI group was 27 (IQR=21, 33). After controlling for those initial scores, there was no statistically significant difference between the two groups in the amount of change in the state scores from the first to fourth session ( $p=0.706$ ). Given the dramatically higher anxiety scores during the first

TABLE 3. SUMMARIES OF STATE STATE-TRAIT ANXIETY INVENTORY SCORES INITIAL SESSIONS AND FOURTH SESSIONS

	Overall	Usual care	AAI	p
	Median (IQR) min, max	Median (IQR) min, max	Median (IQR) min, max	
Child with cancer	(N=19)	(N=10)	(N=9)	
First session	29 (27, 32) 23, 46	30 (27, 33) 23, 46	28 (26, 33) 26, 38	0.621 <sup>a</sup>
Fourth session	29 (25, 33) 20, 46	26 (24, 31) 20, 38	30 (24, 39) 20, 46	0.411 <sup>b</sup>
Change from first (state)	-1 (-4, 2) -13, 19	-3 (-6, 0) -13, 8	1 (-3, 3) -6, 19	0.170 <sup>c</sup>
Adult	(N=21)	(N=11)	(N=10)	
First session	34 (25, 48) 20, 71	48 (34, 59) 23, 71	27 (21, 33) 20, 47	0.003 <sup>a</sup>
Fourth session	30 (25, 44) 20, 58	33 (30, 44) 28, 58	25 (22, 41) 20, 52	0.035 <sup>b</sup>
Change from first (state)	-2 (-9, 2) -35, 21	-7 (-18, -2) -35, 21	-1 (-3, 7) -4, 14	0.706 <sup>c</sup>

<sup>a</sup>Mann-Whitney test.

<sup>b</sup>Mann-Whitney test, does not control for study group difference in first session scores.

<sup>c</sup>Regression: Study group difference after controlling for first session scores.

clinic visit for the UC group, the scores for those parents tended to decrease toward the levels observed for the parents in the AAI group after the first session with the dog yet still remained higher after four visits (median=33 vs. 25 respectively,  $p=0.037$ ) (Table 3 and Fig. 3).

## Discussion

Children with advanced cancer and their caregivers experience significant stress and anxiety. These psychological symptoms worsen toward the end of life and, if undertreated, lead to further patient and caregiver suffering. Our study evaluated AAI as a means to reduce anxiety experienced by patients and families.

We found no significant difference in STAI-CH State subscale scores in the first week in child participants between our two study groups. However, there was a statistically significant difference in STAI State subscale scores in the first week in caregiver participants, with lower anxiety in the AAI-intervention group. Interestingly, there was no statistically significant difference between caregiver groups in baseline STAI Trait subscale scores, indicating that proneness to anxiety in both groups was similar. Therefore, the lower initial STAI State scores among AAI group caregivers may suggest that awareness of continued participation in AAI may have been impactful enough to decrease caregiver anxiety scores. This finding is consistent with prior qualitative studies that have explored caregiver perceptions of AAI,

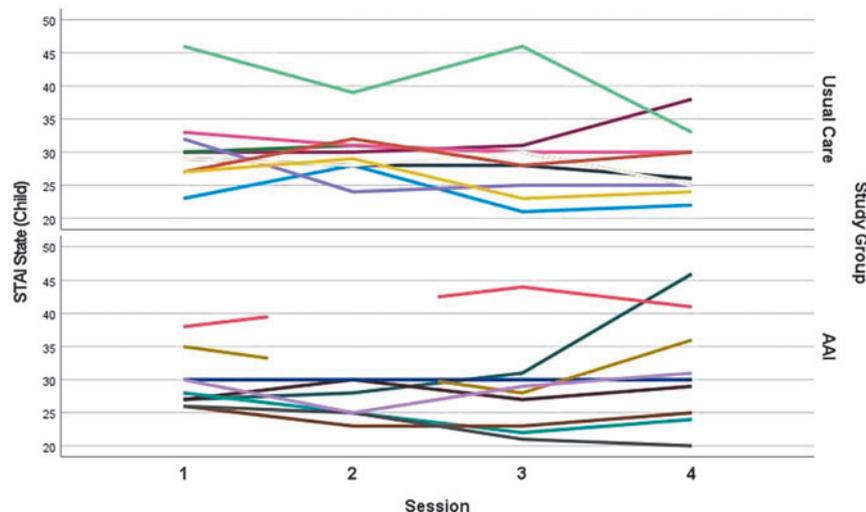
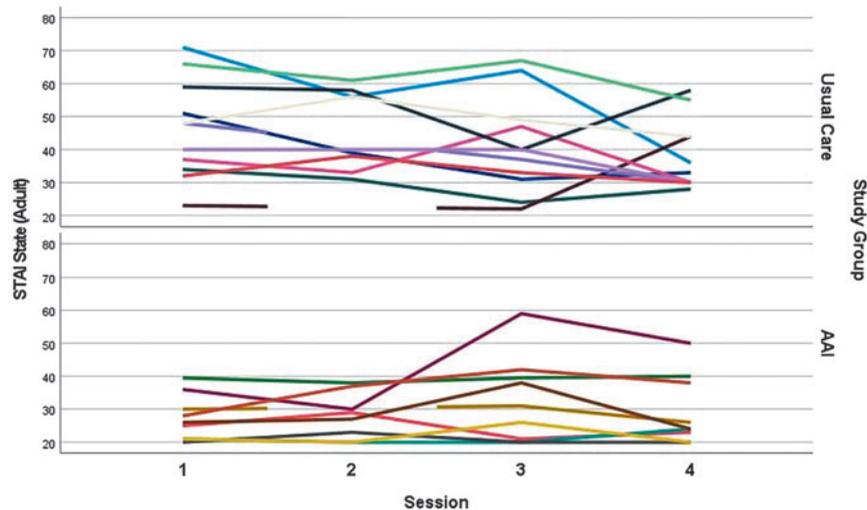


FIG. 2. STAI-CH State subscores of child participants across four sessions in UC groups and AAI groups.



**FIG. 3.** STAI State subscores of adult participants across four sessions in UC groups and AAI groups.

noting a common theme for parents is that knowledge of seeing a dog in the hospital or clinic lessens anxiety for children, which in turn may lessen parental anxiety.<sup>21,22</sup>

While we found a significant difference in initial caregiver STAI State scores, we did not see a statistically significant difference in anxiety scores over time in either the UC or AAI groups in children or caregivers. There are several confounding factors and limitations to consider. First, we did not obtain a blinded initial State anxiety assessment due to survey implementation after randomization to study groups. Therefore, we cannot know whether State anxiety scores were dissimilar in caregiver groups at baseline before randomization or if the difference is attributable to the AAI intervention. Additionally, only the UC group received a financial incentive, which may have had some effect on anxiety in the UC group alone. The relatively low baseline Trait and first visit State anxiety scores in our patient populations were also a limitation. While we know from prior research that our targeted population is at risk for high anxiety, our cohort of patients and caregivers had relatively low initial anxiety scores. Trait anxiety scores in both children and adults were toward the lower end of the scale, as were most State anxiety scores. With lower initial anxiety scores, it is more challenging to demonstrate statistically significant change over time. Furthermore, any change in anxiety scores may have been impacted by changes to patient medical condition over the course of study. Lastly, the small sample size may have had an impact on our results. We may have failed to detect a statistically significant difference between the UC and AAI groups due to insufficient statistical power. Recruitment was impacted by the COVID-19 pandemic, as recruitment and data collection were paused for approximately five months when hospital visitation was restricted.

Importantly, a strength of our study is that it is one of only a few longitudinal randomized controlled trials in the literature focusing on AAI-based interventions in pediatric patients with advanced cancer. Our results demonstrate the feasibility of conducting research in this patient population, which we hope will further the impetus for study in this area. While we did not demonstrate a statistically significant difference in

change in anxiety scores between groups, the difference in initial STAI State anxiety scores for caregivers may indicate a positive effect of AAI in reducing anxiety surrounding appointments through anticipation of seeing a therapy dog. Addition of qualitative data will be important in the future to further our understanding of the impact of AAI on caregivers.

For this study, we focused specifically on anxiety in a pediatric oncology population. However, as prior literature has shown, AAI can be an effective therapy for patients with many different chronic illnesses and can affect not only anxiety but communication, quality of life, and even physical symptoms such as pain. Future studies should continue to explore utilizing AAI as supportive care for all vulnerable patient populations. Evaluating AAI and anxiety in siblings or other family members may illuminate areas of need as well. Additionally, we did not explore whether underlying cultural or socioeconomic factors have any bearing on AAI-intervention and its effectiveness. Another interesting area of future study would be to evaluate whether pet ownership has any effect on AAI's impact on anxiety in a pediatric population, as it has been shown to have a significant effect in adults.<sup>16</sup>

## Conclusion

Our results demonstrate the feasibility of conducting AAI-based research in this patient population and the potential for AAI to reduce anxiety in pediatric patients with relapsed or refractory cancer and their caregivers. Further research is needed to continue to evaluate AAI's effectiveness and role in the care of these patients.

## Acknowledgments

We thank the children and their parents who kindly participated in this study.

## Authors' Contributions

A.B.M.: Writing—original draft preparation, M.J.G.: Conceptualization, Writing—Reviewing and Editing,

T.F.A.: Writing—Reviewing and Editing, B.A.C.: Writing—Reviewing and Editing, M.S.D.: Data analysis, Writing—Reviewing and Editing, J.L.N.: Writing—Reviewing and Editing.

### Funding Information

This study, in part, was funded by the Human-Animal Bond Research Institute (HABRI, grant number HAB18-010). This study also utilized REDCap for data collection, and thus benefitted from National Center for Advancing Translational Science/National Institutes of Health Support (grant number UL1 TR000445).

### Author Disclosure Statement

No competing financial interests exist.

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