

Canines and Childhood Cancer

*Pilot Study Report
Executive Summary*



American Humane Association™
The nation's voice for the protection of children & animals™

Introduction

Since December 2011, Zoetis and the Pfizer Foundation have sponsored American Humane Association in developing and executing the *Canines and Childhood Cancer (CCC) Study* to investigate the effects of animal-assisted therapy (AAT) on pediatric oncology patients, their families, and the therapy dogs who visit them. In collaboration with children's hospitals and universities across the country, American Humane Association has completed a comprehensive needs assessment, including a literature review on AAT and pediatric oncology (visit www.caninesandchildhoodcancer.org), as well as a pilot study to inform the design and implementation of a full clinical trial scheduled to begin in late 2013.

Unlike the majority of existing research in the human-animal interaction field, this rigorously designed pilot study took place at multiple sites, and incorporated a randomized control cohort and validated instruments to evaluate how the addition of AAT to Acute Lymphoblastic Leukemia (ALL) treatment impacts the distress levels of children, parents/guardians, and therapy dogs. The *CCC Study* is anticipated to be a milestone in understanding the vital bond shared between people and animals.



Background and Rationale

Children with cancer and their families not only cope with physical concerns, but are also prone to psychosocial and behavioral issues, such as stress and anxiety (Fotiadou, Barlow, Powell, & Langton, 2008; Norberg & Boman, 2008). To date, few evidence-based studies have either critically examined or recommended adjunctive interventions to help the entire family cope with the distress that often accompanies a childhood cancer diagnosis. AAT is a complementary treatment option that has promise for children with cancer and their families. Research suggests that animals can provide numerous benefits for people from all ages and walks of life, including stress reduction and social support (Fine, 2010; Endenburg & van Lith, 2011; Nimer & Lundahl, 2007).



However, while therapy dog programs are common in hospitals throughout the United States, existing evidence concerning the effectiveness of AAT in pediatric oncology settings is very limited. In addition, there is a general lack of scientific research on how AAT may impact therapy animals. American Humane Association believes that rigorously filling both of these research gaps is crucial if AAT is to be considered an effective, safe and ethical mode of adjunctive treatment for children and families in need of healing care.



CCC Pilot Study

In order to fully prepare for a clinical trial, it was necessary to first pilot the *CCC Study*. The six month pilot study ran from January through June of 2013 at East Tennessee Children's Hospital (in conjunction with the University of Tennessee's College of Veterinary Medicine) in Knoxville, TN and St. Joseph's Children's Hospital in Tampa, FL. A total of





six children and six parents (one per child) participated in the pilot study; three were enrolled at each site and three were randomly selected to receive AAT in addition to their standard-of-care treatment.

Pilot Aims

The primary goals of the pilot were to **1).** Address the feasibility of conducting a randomized control trial utilizing AAT within multiple pediatric healthcare settings; and **2).** Develop recommendations for revisions to the study design leading up to a final research protocol for the full clinical trial.

Pilot Hypotheses

1. Pediatric cancer patients with ALL (aged 3-11 years) and their parents/guardians who receive AAT will experience less distress throughout the course of their treatment sessions than patients who do not receive AAT.
2. Participating therapy dogs will exhibit minimal distress over the course of the *CCC Study*.

Pilot Methods

Children and parents in the treatment group visited with their particular therapy dog for approximately 20 minutes once a week during their regularly scheduled appointments in the outpatient clinic. In order to measure distress, those in both the control and treatment groups completed two psychosocial surveys; had their heart rate variability and/or blood pressure measured; and/or were videotaped at designated time points over a 3-4 month data collection period.

Animal-handlers collected their dog's saliva at the beginning of the study to establish a baseline cortisol measurement, and then again after each AAT session. Handlers also completed a self-report form on their dog's behavior and the activities that occurred during the session. Additionally, the dog's behavior was videotaped at designated time points throughout the pilot study for comparison with their salivary cortisol levels and handler-documented behavior.

Main Pilot Findings and Lessons Learned

Overall, American Humane Association found that it was feasible to conduct a randomized control trial utilizing AAT at multiple pediatric oncology settings. Both pilot sites were active and supportive participants, and helped to successfully facilitate family and handler recruitment, pilot protocol, and data collection (including canine saliva) and transfer. This is noteworthy, given that this type of rigorous study design in children's hospitals is a rarity for AAT research. In fact, research indicates that gaining access to a clinical setting, much less multiple settings, is a key challenge in conducting sound AAT studies (Johnson, Odendaal & Meadows, 2002; Kazdin, 2010). With careful planning and training, as well as cooperative funding and site partnerships, researchers can greatly alleviate feasibility challenges.



As expected, the pilot study was also successful in highlighting several areas for study design optimization in preparation for the full clinical trial. For example, in order to increase the pilot study's small sample size, the eligibility criteria will be expanded to include children aged 3-12 years who come into the clinic regularly for chemotherapy treatment (regardless of their cancer diagnosis). Due to a lack of observable distress among pediatric patients, researchers will instead measure stress, anxiety, and health-related quality of life. As such, additional research instruments will be incorporated into the full clinical trial design to address the expanded research foci. Other important lessons learned from the pilot included increasing the frequency of data collection and slightly decreasing the duration of the AAT sessions for the benefit of the therapy dogs and very young patients.



Next Steps

At the conclusion of the pilot study, American Humane Association and Zoetis are now one step closer to providing meaningful evidence on the healing power of human-animal relationships. These pilot findings will inform the implementation of a rigorous clinical trial in 3-5 pediatric healthcare settings by the end of 2013. The full clinical trial is expected to last for 14 months, with findings being distributed in 2015. If you have questions about the *CCC Study*, please contact Amy McCullough at American Humane Association (amym@americanhumane.org).





American Humane Association™
The nation's voice for the protection of children & animals™