

zoetis™

American Humane Association™

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



Canines and Childhood Cancer Study

University of Tennessee Veterinary Social Work Summit

April 11, 2013

Agenda

- Study Rationale
- Study Sponsor and Research Team
- Literature Review/Focus Group and Interview Findings
- Pilot Study Design
- Next Steps



The Issue of Childhood Cancer



- Cancer is the number one cause of death by disease for children
 - Approximately 12,000 children were diagnosed in 2012
 - 5-year survival rate is 83%
- Quality of life for the entire family remains a concern
- Evidence-based interventions to help the family during this experience are needed

Why the Canines and Childhood Cancer (CCC) Study?

- Animal-assisted therapy (AAT) is a promising intervention to help families dealing with childhood cancer
- Studies regarding human-animal interactions date back to the late 1970's
 - Primarily anecdotal
 - Lack scientific rigor
- As a result, AAT has received:
 - Limited recognition by medical professionals
 - Limited support from government funding agencies



CCC Study Features



- Randomized control cohort
- Multi-site
- Large sample size
- Validated measurement instruments

American Humane Association

- The country's first national humane organization
- The only charity dedicated to the protection of both children and animals
- Mission since 1877:
 - Ensure the welfare, wellness and well-being of children and animals
 - Unleash the full potential of the bond between humans and animals to the mutual benefit of both





- Formerly the animal health business of Pfizer
- Working to ensure a safe, sustainable global food supply
- Helping dogs, cats and horses live healthier and longer lives

Our Study Approach

CCC Study Plan

Stage I

- Comprehensive Literature Review and Focus Groups/Interviews
- Pilot Study Design
- Site Recruitment/IRB and IACUC

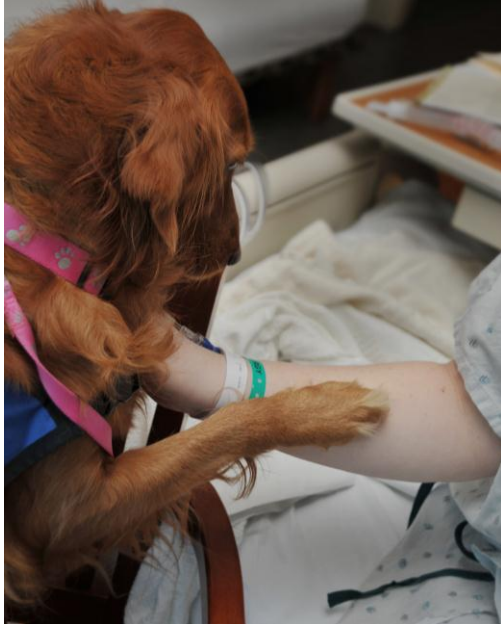
Stage II

- Conduct Pilot Study
- Data Analyses & Report Generation

Stage III

- Finalize Full Trial Study Design
- IRB/IACUC Full Trial Processes
- Conduct Full Clinical Trial

Literature Review



- Published in January 2012
- Intended to serve as a study background and a resource to the pediatric oncology and human-animal interaction fields
- Covers more than 150 literature sources
- Reviewed by experts in pediatric medicine, animal welfare and behavior, and human-animal interaction
- Available at: www.caninesandchildhoodcancer.org

Focus Group and Interview Process

- Focus groups and interviews were conducted with three sites to inform study design and planning:
 - East Tennessee Children's Hospital in Knoxville, TN
 - University of TN College of Veterinary Medicine
 - Monroe Carell Jr. Children's Hospital at Vanderbilt in Nashville, TN
 - St. Joseph's Children's Hospital in Tampa, FL



Summary of Findings from Literature Review, Focus Groups, and Interviews

Brief Overview of Pediatric Oncology

- Over the past 2 decades, while the incidence of cancer has increased slightly, the mortality rates from cancer have drastically decreased
- Leukemia is the most common form of all childhood cancers
 - Most prevalent in children under the age of 10 years, peaked around age 3-4 years
 - Treatment is approximately 2 years for females and 3 years for males
 - Nearly 2,500 new cases are diagnosed in the U.S. every year



Effects of Cancer Treatment on Children



- Distress and anxiety
- Anger
- Body image, self-esteem, and identity issues
- Depression
- Academic performance
- Fear of infection, relapse, or death
- Immunosuppression
- Mood and behavior swings due to steroids
- Pain and discomfort
- Social isolation
- Worry about family wellbeing
- Improved social functioning and confidence

Effects of Childhood Cancer on Families

- Distress and anxiety
- Depression and grief
- Fear of infection, relapse, and death
- Guilt
- Post traumatic stress symptoms
- Financial and employment concerns
- Social isolation and loneliness
- Strain on relationships
- Hard on siblings
- Increased family closeness
- Weight gain and decreased physical activity



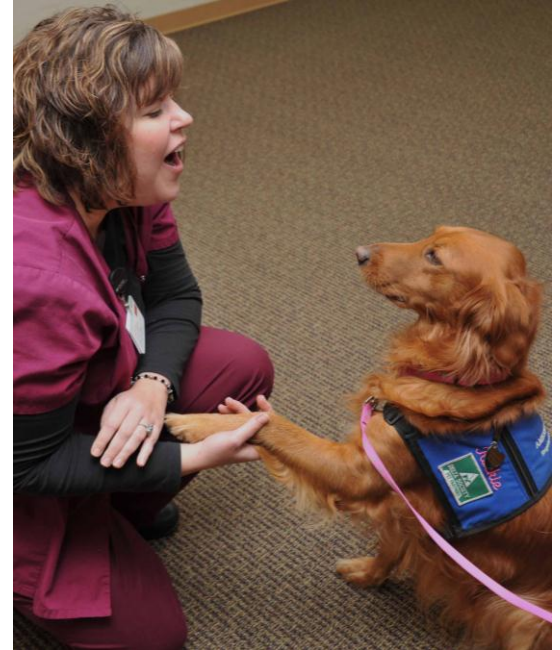
Benefits of Animal-Assisted Therapy



- Reduced stress and anxiety
- Distraction from pain and worry
- Decreased heart rate and blood pressure
- Help with coping
- Mood elevation
- Decrease loneliness
- Facilitate rapport and social interaction between people
- Normalize the hospital experience
- Motivate active participation in the treatment process

Safely Implementing AAT in Hospitals

- Human safety and well-being
 - Risk management and infection control policies and procedures
- Therapy dog safety and well-being
- Animal-handler team training and certification
- Setting and participant selection



Typical Therapy Dog Visit in Pediatric Oncology



- Handlers and their dogs visit from room to room and in common areas
- Interact with both patients and families
- Handlers and dogs typically visit once a week
- Length of time with each child and family varies
- Handler's role is to advocate for their dog
- Typical conversation is around the dog's characteristics and about the family's pets
- Activities may include petting, brushing, and giving the dog commands

Current State of AAT Research

- Rigorous and evidence-based research in the field of AAT continues to be lacking
- Much of our understanding of AAT effectiveness is based on anecdotal information
- Issues with developing and conducting AAT research include:
 - Gaining access to clinical settings
 - Timely IRB and IACUC approval
 - Recruiting large study samples
 - Multiple settings
 - Employing appropriate study instrumentation
 - Lack of standardized AAT protocols
- Lack of research on the effects of AAT on therapy dogs

Pilot Study Design

Designing a Study to Address the Main Findings

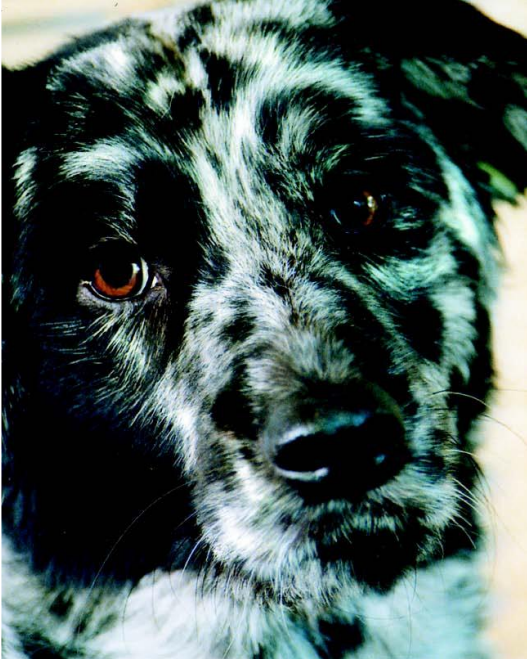
Main Findings

- Pediatric cancer patients and parents experience substantial distress
- Acute lymphoblastic leukemia (ALL) is the most common form of childhood cancer
- Very little rigorous research to quantitatively measure the efficacy of AAT
- Very little research addressing the impact of sessions on therapy animals

Study Design

- Distress as the target for the AAT protocol
- Population identified as ALL patients
- Study design based on standard clinical efficacy studies
- Measure impact on the therapy dogs to inform standards of practice

Hypotheses



Children: Pediatric Acute Lymphoblastic Leukemia (ALL)

H₁: Pediatric cancer patients with ALL who receive AAT will experience less **distress** throughout the course of their treatment sessions than patients who do not receive AAT.

Parents/Primary Caregivers

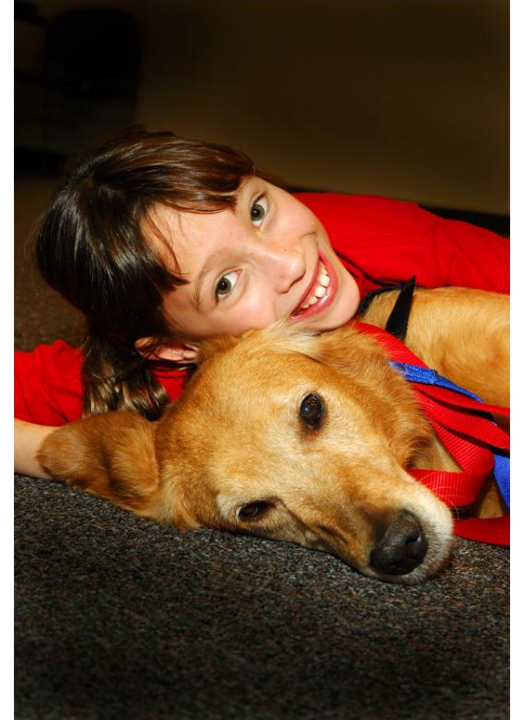
H₂: Parents/primary caregivers of pediatric cancer patients with ALL who receive AAT will experience less **distress** throughout the course of their child's treatment sessions than parents of patients who do not receive AAT.

Therapy Dogs

H₃: Participating therapy dogs will exhibit minimal **distress** over the course of the CCC study.

Study Design Overview

- Randomized controlled clinical study
 - Control cohort receives standard-of-care
 - Study cohort receives standard-of-care plus AAT
- Multi-site
 - Staggered start dates
- Relatively large sample size
 - Goal is at least 100 participants
- Validated psychosocial and biological instrumentation



Piloting the Study Design



- Address the feasibility of conducting a randomized control trial utilizing AAT within a pediatric healthcare setting
- Determine how to address issues of scientific integrity and protocol fidelity
- Develop recommendations for revisions to the protocol leading up to a final research design for a full clinical trial

Sites

- East Tennessee Children's Hospital in Knoxville, TN
 - In conjunction with University of TN College of Veterinary Medicine
- Monroe Carell Jr. Children's Hospital at Vanderbilt in Nashville, TN
- St. Joseph's Children's Hospital in Tampa, FL



Overview of Study Implementation Steps



- Identify child and determine eligibility
- Approach family and perform consent process
- Receive group assignment and identifier
- Determine session schedule
- Match child to dog (if in treatment cohort)
- Inform family
- First session occurs

AAT Protocol for the Pilot

- Participating child in the treatment group is matched with an animal-handler team
- Visits occur approximately once a week when they come in for their treatment
- Interaction with therapy team is 20 minutes, +/- 10 minutes
- Full data collection occurs weekly during the child's induction treatment phase, then once every two months
- Activities during session with the therapy dog are what typically occurs during a visit, but are documented for tracking purposes



Patient Instrumentation



Observational Scale of Behavioral Distress

- Video observation and coding by American Humane Association

Blood Pressure

- Blood pressure taken prior to the dog entering the treatment session
- Then again just prior to the dog exiting the treatment session
- Similar timing for control patients

Patient Instrumentation

Heart Rate Variability

- A Polar Heart Rate Monitor is used during the scheduled sessions
- The child wears the chest strap
- The watch and chest strap are removed when the dog leaves the session
- Similar process for control patients



Parent Instrumentation



Demographic Sheet

- Collected at the time of, or shortly after, randomization and ID assignment

Heart Rate Variability

- Same process as with the child

Parent Instrumentation

Pediatric Inventory for Parents



- Administered at any time during or immediately after the session
- Contains a list of 42 difficult events which parents of children who have a serious illness sometimes face
- Parents circle **HOW OFTEN** the event has occurred for them in the past 7 days and rate how **DIFFICULT** the event was/is for them

Parent Instrumentation

State Trait Anxiety Inventory

- Administered at any time during or immediately after the session
- Contains 20 statements for the caregiver to indicate how they are feeling at that moment on a scale from “Not At All” to “Very Much So”



Handler Instrumentation



Demographic Sheet

- Includes dog's age, breed, years of experience

Self-Reports

- Completed at the conclusion of each session
- Handler indicates their perception of their dog's stress level
- Note what activities took place and duration of the session

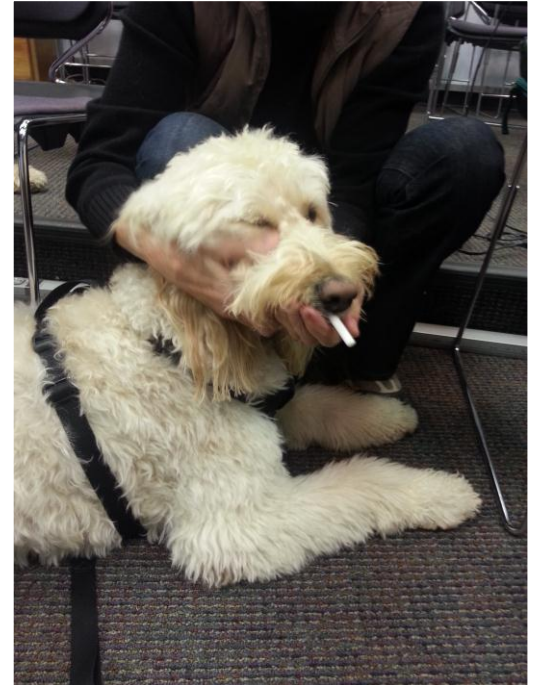
Therapy Dog Instrumentation

Saliva

- Salivary cortisol used as a measure of stress response
- Saliva collected 20 minutes after the session begins
- Compared to a baseline measure
- Shipped to Salimetrics for analysis

Ethogram

- Video observation and coding of the dog's behavior by American Humane Association



Next Steps for the Study



- Continue collecting pilot data through the end of June 2013
- Analyze pilot study data and generate report
- Recruit 5 or more full clinical trial sites
- Optimize instrumentation and protocol
- Complete IRB and IACUC processes
- Launch full trial in late 2013

American Humane Association™

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



Contact:

Kevin Morris, Ph.D.

Co-Principal Investigator

American Humane Association

Email: kevinm@americanhumane.org

Molly Jenkins, M.S.W.

Research Analyst

Children's Innovation Institute and CCC Study

American Humane Association

Email: molly.jenkins@americanhumane.org

Amy McCullough, M.A.

Co-Principal Investigator

National Director of Animal-Assisted Therapy

American Humane Association

Email: amym@americanhumane.org

Ashleigh Ruehrdanz, M.P.H.

Research and Evaluation Specialist/IRB Administrator

Children's Innovation Institute and CCC Study

American Humane Association

Email: ashleighr@americanhumane.org