• 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
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
### 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)

$H_1$: 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

$H_2$: 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

$H_3$: 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
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