PROTOCOL IRB22-1218

Title:
Feasibility of a dog training therapy program in UC outpatient youth receiving psychiatric services

1. Background.

Over the past 15 years there has been an explosion in programs involving animal-assisted activities (AAA) and animal-assisted interventions (AAI) across multiple settings, including college campuses, hospitals, prisons, and residential facilities. The growing interest in the potential of human-animal interaction programs to decrease stress and increase positive outcomes has further led to interests in using animals in therapeutic settings. There is a particularly compelling need for accessible treatment options for youth with mental illness, as children's mental health needs are often under-recognized and under-treated[1] and only a small minority of youth who need mental health services will actually receive treatment[2].

Human-animal interaction (HAI) programs to reduce psychological distress in children are increasingly common in medical[3-6] and educational[7, 8] settings. HAI programs are appealing because they can be made accessible to large populations, require less training and expertise in comparison to traditional therapies, and enjoy positive public perception[9]. HAI programs in children may also be perceived as less stigmatizing than traditional therapies[10]. Despite the popularity of HAI programs, research on the effectiveness of these programs suffers from many methodological limitations, including the use of small, select samples, reliance on self-report measures, and lack of adequate control comparisons[9, 11]. Thus, there is need for rigorous research designs to evaluate HAI in the treatment of pediatric mental distress[12], particularly on whether the use of animal-assisted therapy (AAT) can enhance the treatment of youth with mental disorders beyond established treatments[13].

AAT differs from AAI and AAA in several important ways. First, AAT is typically considered an adjunct intervention designed to supplement primary therapy[14]. Second, AAT is a specific form of AAI where integration of the animal into treatment is done in a structured and goal-oriented way meant to facilitate the delivery of the primary intervention[15]. The rationale for using AAT as an adjunct to traditional psychotherapy is based on two complementary mechanisms. Social support theory posits that the presence of companion animals has a calming effect that can increase feelings of social support[16, 17], thereby decreasing perceptions of stress. Even unfamiliar animals may offer non-evaluative support in stressful situations that is superior to social support received from humans[18, 19]. Attachment theory posits that animals may act as transitional objects which allow children to establish attachment bonds with animals that can extend to attachment bonds with other humans[20-22]. Attachment due to the human-animal bond may lead to heightened feelings of child security, further strengthening the bond between child and therapist[23-25].

A recent review of animal-assisted therapies (AAT) for youth at risk for mental health problems reported 24 studies published between 2000-2015[26]. Inclusion criteria included studies of youth aged 21 or younger at risk or with mental health symptoms, studies with a defined control or comparison group, and studies that included AAT as part of the child or adolescent's treatment. Eleven of the 24 studies examined equine therapies, while 10 studied the effects of canine therapy. Most (75%) of studies delivered AAT in outpatient settings. Almost half of studies used a Randomized Controlled Trial (RCT) design to assign youth to the intervention group. Overall results from studies were mixed, with 8 demonstrating positive effects associated with

the AAT, 10 reporting mixed effects, and 6 demonstrating no effect. The majority of AAT studies using equine therapy used a semi-structured curriculum that shared the same goals of regulating youth emotional or behavioral functioning through structured, goal-directed program activities. While there was consistent support for the effectiveness of equine therapy, particularly among youth with autism spectrum disorder, equine therapy is costly, difficult to scale, and may not be readily available for youth across different socioeconomic strata.

In contrast, canine-assisted therapies are easier to scale and are widely available. However, the review indicated that the effects of studies using canine-assisted therapies on youth outcomes were more mixed. One interesting observation was that the majority of the canine-assisted therapies used unstructured activities, such as presence of the dog, or grooming, petting, and playing with the dog. This raises the question whether incorporating canines into a structured, goal-oriented AAT program would be more likely to show positive results.

Over 10 years ago, the Chicago non-profit organization, Canine Therapy Corps, Inc. (CTCorps) developed a canine-assisted therapy program based on structured, goal-oriented activities related to dog training. This program became the Rebekah Ferguson Recovery & Care Canine-Assisted Therapy program. This pioneering program uses principles of co-leadership, where youth learn to master certain skills through interactions with trained, experienced dog-handler teams who are supervised by a Canine Behavior expert and a Clinical supervisor with expertise in mental health. The overall goals of this program are to help participants overcome trauma, build positive relationships, learn personal responsibility, and develop positive life skills. The curriculum for the Recovery & Care program was published in 2015[27], and the program has been successfully deployed with hundreds of children and adults over the past decade.

The Recovery & Care program shares many core features with principles underlying cognitive-behavioral therapies. Both therapies emphasize the development of a good client-therapist relationship, although in the case of the Recovery & Care program, the primary relationship is between the participant and the therapy dog. Both therapies are structured, time-limited, goal-oriented and problem-focused, and emphasize present behaviors and cognitions. Both therapies emphasize collaboration and active participation, and both use a variety of techniques to change thinking, mood, and behavior. A primary difference between the two approaches is that participants in the Recovery & Care program are not directed to identify, evaluate, and respond to dysfunctional thoughts and beliefs. Instead, the learning that takes places happens in the background as participants begin to adapt their behaviors to better meet the goals of the training activities. In this way, the Recovery & Care program also shares key features with social-learning programs, where participants learn social-emotional learning and build positive social interaction skills while pursuing a common, goal-oriented activity[28, 29].

The developers of the Recovery & Care program argue that because of the nature of the skills needed for successful dog training, the program has the most impact on participants' self-discipline and emotional management[27]. Importantly, according to the NIMH RDoC approach, deficits in these dimensions underlie a host of mental health disorders. Indeed, another way that the present project will extend prior research is to recruit participants not on the basis of diagnostic categories of mental illness, but rather on profiles of symptoms representing deficits in at least one of these two key areas. Additionally, after observing the program in 100s of participants, program facilitators also strongly believe that participating in the program builds a sense of mastery, resulting in greater self-confidence and higher self-esteem[27]. Thus, in the proposed project we will focus primarily on outcome measures that best match the goals of the Recovery & Care intervention program.

2. Purpose or hypothesis of the study, including potential knowledge to be gained.

2.1. Purpose.

Over the past several years there has been an increase in the use of animal-assisted activities (AAA) and animal-assisted therapies (AAT) aimed at treating youth with social, emotional, and behavioral problems. To date, however, there is limited empirical investigation of whether these programs have additional therapeutic effects beyond the use of traditional therapies. Moreover, many AAA/AAT program are unstructured and/or use animals as an adjunct to the therapy process (i.e., by having the animal present during therapy sessions). This makes it difficult to understand the mechanisms through which AAA/AAT programs may improve outcomes.

The Recovery & Care Canine-Assisted Therapy curriculum, developed by the Chicago-based Canine-Therapy Corps organization (CTCorps), is a 6- to 12-week program of structured, goal-oriented activities focused specifically on dog training. (Note that for activities under the current protocol, we will be evaluating the 6-week version of the Recovery & Care program). The Recovery & Care program has been implemented in several populations of vulnerable youth and adults, including youth residing in a residential treatment center for maltreated youth with severe emotional and behavioral disorders. To date, however, the feasibility of expanding the Recovery & Care program to youth with behavioral and emotional problems who are receiving **outpatient** psychiatric and psychological services has yet to be evaluated.

Thus, the goal of this study protocol is to use a Randomized Control Trial (RCT) to test for feasibility, acceptability, and initial efficacy of the Recovery & Care Canine-Assisted Therapy program delivered in pediatric patients currently receiving outpatient psychological/psychiatric care in the department of Psychiatry at the UCMC. We will compare outcome and feasibility measures to a similar group of pediatric patients who will be randomly assigned to an active canine-interaction intervention condition.

We believe that the Recovery & Care program directly promotes skills of emotion regulation and impulse control as youth engage in progressively more advanced activities in areas of dog obedience and agility. We will measure these skills as primary outcomes using computer-based neurocognitive tests. We also believe that by mastering the activities in the program, youth gain confidence which increases self-esteem, which will be measured using standard self-report instruments.

2.2. Specific Aims and Hypotheses.

The specific aims for this pilot study are to examine the feasibility, acceptability, and initial efficacy of an established, 6-week canine-assisted therapy program (Recovery & Care) delivered to youth aged 12-17 who are currently receiving outpatient treatment for mental health problems at the UCMC. We will use RCT to compare outcomes for the group enrolled in the Recovery & Care intervention to a group of youth receiving an active canine-interaction intervention. Specific hypotheses include:

a) Youth enrolled in both the active and control interventions will show elevated rates of positive mood immediately following program sessions.
b) Attendance rates will be higher and study attrition rates will be lower among youth in the Recovery & Care intervention compared to youth in the active control intervention.
c) In comparison to control youth, youth in the Recovery & Care intervention will show fewer behavioral problems, greater emotion regulation, greater impulse control, and higher self-esteem at the 2-week follow-up after the end of the intervention.

2.3. Potential Knowledge to Be Gained.

This will be one of the first studies to examine the effects of a structured, goal-oriented canine-assisted dog training program on vulnerable youth and the first study to specifically evaluate the CTCorps' Recovery & Care Canine-Assisted Therapy program in outpatient youth with emotional and behavior problems. If successful, the Recovery & Care program could serve as a model for developing similar programs in other locations. Moreover, the knowledge gained through this project will be helpful for the broader clinical understanding of how dog therapy programs in general, and the Recovery & Care program specifically, help youth develop the skills necessary to maintain a healthy lifestyle.

3. Description of protocol methodology

3.a Study design:

The study uses a Randomized Control Trial (RCT) design, with half of youth assigned to the Recovery & Care Canine-Assisted Therapy program and half of youth assigned to an active canine-interaction control condition. This is an unblinded study. Youth, study investigators, and research project staff will all know which intervention condition the youth has been assigned to.

3.b. Sample:

Subjects for the current study will be youth aged 12-17 who are currently receiving or who have received treatment for mental health in the past year, from the Department of Psychiatry at UCMC, who have current difficulties in behavior and/or emotion regulation. Subjects also include a single parent/legal guardian for each youth enrolled in the study.

We will recruit up to 72 subjects between the ages 12 years, 0 months, and 17 years, 8 months along with a single parent/legal guardian for each child (N=72). The total recruitment N=144. Our goal is to have data from a final analytic sample of 24 youth in the experimental Recovery & Care program group and 24 youth in the active canine-interaction control group (N=48). For both conditions, we will include all youth who are eligible for the study after the baseline assessment and who attend at least one session of the relevant intervention. If there are eligible youth who complete the baseline assessment but do not attend at least one canine intervention session, they will be replaced by another youth in a later cohort. If a subject in either the experimental or control groups is found to be ineligible after the baseline assessment, they will be removed from the study and replaced by another subject.

The sample N was determined primarily by capacity limitations in implementing the Recovery & Care program and evaluating the program within a 2-year NIH R21 grant award. We have budgeted for enough dog-handler teams and staff to support 8 youth in each experimental cohort and 8 youth in each control cohort (total N=16 per study cohort). We plan to complete up to 4, 6-week study cohorts during the course of the 2-year funding period. Ideally, youth will be studied in 3 cohorts of N=16 youth subjects in each cohort (8 per each treatment condition), although additional cohorts may be necessary to achieve the final study N.

Subjects will include females and all racial/ethnic groups will be included.

A priori power calculations based on paired t-tests indicate 80% power to find significant effects in the medium-to-large range, i.e., Cohen's d' = 0.41 to 1.00, for a final analytic sample N=48.

3.c. Recruitment*:*

Recruitment for this study will be done with advertising fliers placed in locations near UCMC child and adolescent psychiatric & psychological clinics.

We will also recruit subjects through medical records. Children who meet the age and diagnostic inclusion/exclusion criteria and who have received psychiatric and/or psychological services from the University of Chicago department of Psychiatry within the past year will be eligible for inclusion. Names of potential patients will be sent to the respective attending clinicians to confirm that the child is a potential candidate for the study. Once confirmation has been obtained, the parent/legal guardian will be sent an IRB-approved recruitment letter and study flier. Physicians will not be informed whether or not their patients participate in the study.

3.d. Study activities overview*:* This section provides an overview of study activities. Additional details are provided below in sections 3.f through 3.k.

Screening: A parent/legal guardian will complete a brief screening questionnaire online to determine initial eligibility, followed by a more extensive phone screen for eligibility.

Baseline assessment: The baseline assessment will occur onsite in the PI's laboratory, although there is an option to complete the consent/assent and a portion of the baseline assessments online.

Research activities include:

1. Written, informed consent/assent procedures.
2. Semi-structured interviews with youth and parent obtaining information on subject demographics, history of pet and animal exposures, and youth animal phobias, history of cruelty towards animals, and medical conditions (asthma, allergies) that may preclude participation.
3. Youth complete a short neuropsych assessment assessing cognitive ability to determine eligibility.
4. Youth complete a self-report measure of executive function to determine eligibility.
5. Youth wear a Empatica watch to assess physiological response during rest.
6. Youth complete self-report measures of social skills and problem behaviors, self-esteem, attitudes towards pets, and (if applicable) relationships with pet dogs.
7. Youth complete two computer-assisted neuropsychological tasks assessing: a) emotion regulation and b) attention and inhibitory control.
8. Parents complete a brief self-report questionnaire on child behavior and emotional problems, attitudes towards pets, and (if applicable) relationships with pet dogs and responsibility for dog care.

Additional screening for eligibility: Following the baseline assessment, child medical records will be examined for diagnosis to determine final eligibility for the program.

Intervention: The intervention activities and associated data collection occur off-site at the Canine Therapy Corps facility. Activities include:

1. Youth who meet eligibility criteria will be randomly assigned to the Recovery & Care experimental condition or the active dog interaction control condition. Both interventions occur once a week for 6 weeks. Full details on these intervention conditions are below.

2. Youth in both conditions will answer a short questionnaire about positive and negative mood immediately before and immediately after each of the intervention sessions they attend.

Follow-up assessment. The follow-up assessment will occur either onsite at UCMC or online through RedCap. Assessments include repeated administration of some of the baseline measures:

1. Youth self-report measures of self-esteem and attitudes towards pets.
2. Youth complete two computer-assisted neuropsychological tasks assessing: a) emotion regulation and b) attention and inhibitory control.
3. Parent report of child behavior and emotional problems.

Additional data collected. In addition to data collected directly from youth and parents, the following data will be collected:
1. We will extract and record selected data from youth subject medical records. This includes psychiatric diagnoses, clinical care history, and any changes in clinical treatment or outcomes occurring during the 10 week study.
2. Project staff will observe all experimental and control intervention sessions and will complete a Fidelity Checklist for each session.

3.e. Timeline of study activities*:*

Up to 2 months before each planned intervention cohort:
Recruitment and initial screening.

Weeks 1-2:
a) Informed consent/assent procedures.
b) Research staff collect baseline data from youth and parents, including review of self-report eligibility measures.
c) Research staff obtain relevant clinical information from subject medical records to confirm eligibility for the study.
d) Random assignment of youth to intervention condition.

Weeks 3-8:
a) Youth participate in either the Recovery & Care intervention or the active canine-interaction intervention. Interventions occur once a week for a total of 6 weeks.
b) Research staff collect mood data from youth immediately before and after each weekly intervention session.
c) Research staff collect fidelity data for each intervention session in both intervention conditions.

Weeks 9-10:

a) Research staff collect follow-up data from all youth enrolled in the study cohort who attended at least one of the intervention sessions.
b) Research staff extract and record relevant clinical information from youth patient medical charts.

3.f. Description of canine-assisted interventions. Each study cohort consists of 6 sessions of activities occurring across a 6-week period. Intervention sessions are delivered in a group setting at the Canine Therapy Corps. Youth in each study cohort are assigned to ***either*** the Recovery & Care intervention or the active canine control intervention.

The Recovery & Care experimental intervention sessions and the active canine interaction control intervention sessions will occur sequentially on the same days using a parallel structure described below. The order of the experimental and active control sessions may be counter-balanced across the different intervention study cohorts.

3.f.i. Experimental intervention. The Recovery & Care Canine-Assisted Therapy intervention is a structured, goal-oriented program developed and implemented by CTCorps staff and volunteers. The Recovery & Care intervention is a 1-hour, 15-minute structured curriculum that occurs weekly across a period of 6 weeks.

During each Recovery & Care session, youth work with CTCorps-affiliated staff, including trained dog-handler teams, a canine behavior expert, and a clinical supervisor experienced in pediatric mental health, to engage in a series of structured activities that progress throughout the intervention.

Week 1 is a “meet-and-greet” session where youth are introduced to all dog-handler teams participating in the program and are asked to select a team to work with for the following sessions. Efforts are made to match youth with their first or second choice of dog. With rare exceptions, youth are expected to work with the same dog-handler team throughout the duration of the 6-week intervention. Each dog-handler team is paired with up to 2 different youth, so youth may work in pairs on the below activities.

Beginning in Week 2, program activities are structured as 20 minutes of basic education, review of prior sessions, and discussion of session goals, 40 minutes practicing skills with the dog-handler team, and 15 minutes reviewing progress and setting goals for the next session.

Week 2 of the 6-week program covers basic foundational skills, understanding how dogs learn and what motivates them, communicating with dogs, and reinforcing good behavior. Session skills include eye contact, hand signals, and basic commands such as “sit” and “down.”

Week 3 builds on obedience training. Discussion topics include distance obedience, vocal volume and tone, body language, and fading reinforcers. Session practice skills include more complex obedience behaviors (stay, come, loose-leash walking) and youth are given a new “trick” that the dog does not know to try to master.

In **Week 4**, youth do dog agility training activities. Discussion topics and session goals include the concept of agility training, the increased use of non-verbal communication skills, and the importance of positive reinforcement. The agility training sessions progress in terms of complexity of number and types of obstacles.

Week 5 is for proofing all skills (obedience, trick, agility) learned in earlier sessions and is a dress rehearsal for the final week graduation ceremony. Youth practice their skills, process

emotions in preparing for the end of the program and participate in unstructured play time with their dog-handler team.

Week 6 is the final graduation session, where youth demonstrate to staff, family, and friends the dog-training skills they learned during the intervention with the dog-handler team.

3.f.ii. Active canine interaction control intervention. Sessions for this intervention are 45 minutes in length and will occur on the same days immediately before or after the Recovery & Care intervention, over the same 6-week period. Each control intervention session will include the same subset of dog-handler teams as those used in the parallel Recovery & Care intervention cohort. Control intervention sessions will also be supervised by the same canine behavior expert and clinical supervisor.

In these control intervention sessions, youth will passively observe the dog-handler teams demonstrating basics of dog obedience and dog agility training that parallel the activities done in the Recovery & Care Canine-Assisted Therapy session that week. Youth will also receive education on basic aspects of dogs (e.g., different breed types, caring for dogs, etc.). Following the education and passive demonstration sessions, youth will be allowed to interact freely with the dog-handler teams.

The control intervention is structured similarly to the Recovery & Care intervention. In week 1, youth will participate in a 45-minute “meet and greet” session where they interact with all the dog-handler teams and will be asked to select their favorite dog. As in the experimental Recovery & Care intervention group above, efforts are made to match each youth with their 1st or 2nd choice, youth interact with the same dog-handler teams throughout the 6-week program, and up to 2 youth may be paired with a single dog-handler team.

In sessions 1-5, following 15 minutes of initial education about basic dog facts, the dog-handler teams will collectively spend 15 minutes displaying the basic obedience and agility training skills presented and practiced in the Recovery & Care intervention, but *without* active youth participation. The final 15 minutes are reserved for unstructured “free-play” activities between youth and the dog handler teams. Week 6 of the control intervention is a 15-minute discussion and Q&A of the program followed by 30 minutes of unstructured free-play session.

3.g. Screening data.

3.g.i. Online screen. Potential parents/guardians who respond to the recruitment letter and/or flier by using the QR code or URL link found on the study flier will be directed to a secure online screener in RedCap with a brief set of questions on initial eligibility and space to record contact information. The online screen is expected to take < 5 minutes to complete. Research staff will then contact parents/guardians for the eligibility phone screen (below).

Parents/guardians who call the study number or use the study email on the recruitment letter and/or flier will skip the online screen and instead go directly to the below eligibility phone screen with research staff.

3.g.i. Eligibility phone screen. All parents/guardians will complete a brief eligibility phone screen with research staff. The screen covers age and medical eligibility for the study and provides places for contact information from parents/guardians who did not complete the online screen as well as scheduling details. The eligibility phone screen should take < 10 minutes to complete.

3.h. Data collected from youth. All data obtained from youth in this study use age-appropriate validated surveys, instruments, and tests.

3.h.i. Data collected through semi-structured interview (baseline only):

1. *Demographics*. Used to describe the study sample.
2. *Dog allergies, asthma*. Used to determine eligibility.
3. *History of pet ownership and exposure to animals*. A series of questions assessing pet ownership, number of pets, species type, and length of ownership, as well as interactions with pets and other animals in other settings, and history of animal injuries and phobias.
4. *Cruelty to Animals Inventory (CAI)*. Validated 12-item instrument to determine eligibility.

3.h.ii. Self-report survey data collected from youth:

1. *BRIEF-2.* (Baseline and follow-up). Standardized, validated 64-item measure of executive functioning that has age-adjusted norms for subscales of emotion regulation and behavioral control. Used to determine eligibility. Youth must score above the age-adjusted clinical cutoffs on at least one of these two subscales to be eligible for the study.
2. *Pet-Attitudes Survey-Modified (PAS-M).* (Baseline and follow-up). Validated, reliable 18-item instrument used to assess youth attitudes towards pets. The PAS-M will be used to determine whether the Recovery & Care intervention improves attitudes towards pets and/or whether the intervention is effective for all youth.
3. *Rosenberg self-esteem scale.* (Baseline and follow-up). Validated, reliable 10-item instrument to obtain self-esteem, a primary outcome of the study.
4. *Social Skills Rating System (SSRS):* Social Skills and Problem Behaviors subscales. (Baseline up and follow up). Validated, reliable self-report instrument published by Pearson with 44 items assessing subscales of cooperation, empathy, assertion, self-control, responsibility, and externalizing behaviors.
5. *Pet Attachment Scale (PAS)*. (Baseline only). Youth who live with dogs will be asked to complete this 27-item, valid, reliable instrument assessing emotional bonds with animals.
6. *Affect/mood.* (Not given at baseline or follow-up; pre-and post-intervention session only; included in separate survey packet). The 10-item Positive and Negative Affect Scale for Children (PANAS-C) will be used to collect data on affect immediately before and after each of the weekly intervention sessions among the group of subjects enrolled in the Recovery & Care program. This is a primary outcome measure.

3.h.iii. Neuropsychological testing.

Neuropsychological testing is done using online tasks available from publishers' websites. For in-person visits, research staff will open the program on a secure project computer and will oversee the child's participation. For virtual visits, subjects will complete the task during a Zoom session with project staff. Subjects will access the task through a website link that will be sent via Zoom chat. Subjects will share their screen so that participation can be monitored.

1. *Cognitive ability.* (Baseline only). Wechsler Abbreviated Scale of Intelligence for children (WASI-C): Vocabulary & Matrix Reasoning subscales (15 minutes). Used to determine eligibility for study. Subjects must score at least 60 on age-adjusted t-value to be included.
2. *Emotion regulation.* (Baseline and follow-up). The Emotional Stroop test (8 minutes) will be used as a primary outcome.
3. *Attention & Inhibitory Control.* (Baseline and follow-up). The Flanker Task (3 minutes) will be used as a primary outcome.

3.h.iv. Estimated time for data collection from youth subjects.

1. *Baseline (total 60 minutes)*.
   Interview (10 minutes).
   Neuropsych testing (30 minutes).
   Self-report surveys (20 minutes).
2. *2-week follow-up assessment post-intervention (total 30 minutes)*.
   Neuropsych testing (15 minutes).
   Self-report surveys (15 minutes).
3. *Weekly intervention sessions (total 5 minutes each week)*.
   PANAS-C intervention mood survey should take < 2 minutes at the beginning and end of each intervention session.

3.j. Data collected from parents/legal guardians (adult subjects).

3.j.i. Data collected through semi-structured interview (baseline only):

1. *Child legal name and DOB*. Used to link child subject to medical records for eligibility.
2. *Adult and family demographics*. Used to describe the study sample.
3. *History of pet ownership and exposure to animals*. A series of questions assessing pet ownership, number of pets, species type, and length of ownership, as well as parent report of child's interactions with pets and other animals in other settings, and history of animal injuries and phobias.
4. *Parent report of child cruelty to animals*. Short form 3-item instrument used to determine eligibility.

3.j.ii. Self-report survey data collected from parents/legal guardians:

1. *Behavioral and Emotional Regulation Subscales (BRIEF-2)* (Baseline and follow-up). Standardized, validated 64-item measure of executive functioning that has age-adjusted norms for subscales of emotion regulation and behavioral control. An outcome measure for the study.
2. *Child Social Behavior Scale (CSBS).* (Baseline and follow-up). This 4-item scale assesses parent report of child prosocial behaviors. An outcome measure for the study.
3. *Children's Attitudes and Behaviors Toward Animals (CABTA)*. (Baseline only). A validated 12-item screening tool used to detect child cruelty towards animals. Use for eligibility.
4. *Pet-Attitudes Survey-Modified (PAS-M)*. (Baseline only). Validated, reliable 18-item instrument used to assess youth attitudes towards pets. The PAS-M will be used to determine whether the Recovery & Care intervention improves attitudes towards pets and/or whether the intervention is effective for all youth.
5. *Pet Attachment Scale (PAS)*. (Baseline only). Parents who live with dogs will be asked to complete this 27-item, valid, reliable instrument assessing emotional bonds with animals.

3.j.iii. Estimated time for data collection from adult subjects.

1. *Baseline (total 35 minutes)*.
   Interview (15 minutes).
   Self-report surveys (20 minutes).
2. *2-week follow-up assessment post-intervention (total 10 minutes)*.
   Self-report surveys on child outcomes (10 minutes).
3. *Weekly intervention sessions (N/A)*.
   No data are collected from adult subjects during the intervention weeks.

3.k. Other sources of data:

3.k.i. Data obtained from child subject medical records. After the baseline assessment, we will examine the child's medical records to make certain there are no exclusionary medical or mental health conditions. To describe the sample population, we will record mental health diagnoses, age of onset, length and type of treatment at UCMC, and any change in treatment or clinical outcomes that occurs during the 6-week intervention.

3.k.ii. Observational data. We will record fidelity to the two dog therapy interventions using a *Staff Fidelity Checklist* developed for this study by the PI. Research staff will record this information directly into RedCap through study tablets during each weekly intervention session. This instrument contains data on the content of the intervention in each week, adherence to program protocol (i.e., goal setting, review, educational, and training activities), as well as any potential adverse events that occur during the course of the intervention. Intervention sessions will not be videotaped or recorded for this study.

4. Probable duration of protocol.

Funding for this project is expected to be released in Summer/Fall 2022. The project period for this study is 24 months (2-year grant). During the 2-year award period, 3-4 study cohorts will be enrolled for an estimated 6 weeks per cohort.

5. Exact location where research is to be conducted (building, room number, etc.).

Recruitment, screening, consent/assent, baseline and follow-up data collection:
Dr. Jacobson's lab suite on 4th floor CLI:
Rooms L457, L458, L459
5841 S Maryland Ave.
Chicago, IL 60637

Intervention sessions, weekly pre- and post-session mood questionnaires, staff fidelity checklists:
Canine Therapy Corps
3918 W Fullerton Ave
Chicago, IL 60647

Data Storage and Analysis:
Dr. Jacobson's (PI) Office
Department of Psychiatry & Behavioral Neuroscience
5841 S. Maryland Ave.
Room L-466D
Chicago, IL 60637

6. Special precautions to be taken by researchers, including dose modifications.

No dose modifications are needed because the study is not using medication.

7. Description of experimental controls and use of placebos.

No placebos are used in this study. The experimental and control conditions for youth are described above in Section 3.f.

For between-subjects analyses, we will compare youth report scores on the BRIEF-2, pet attitudes scale, and self-esteem scale, parent reports of child behavior problems, and youth performance on the emotion regulation and attention/inhibitory control tasks at follow-up for the Recovery & Care intervention group with the active canine interaction control group.

For within-subjects analysis of the Recovery & Care treatment group, scores on the pet attitudes scale, self-esteem scale, and performance on the emotion regulation and attention/inhibitory control tasks will compared at baseline and follow-up. Self-reports of affect/mood will be compared before and after each intervention session.

8. Type and number of experimental subjects, including method of subject selection, randomization, and inclusion and exclusion criteria, if any.

8.a Type and number of subjects: We plan to recruit up to N=72 subjects aged 12-17 who are receiving care at the UCMC department of psychiatry, section of Child & Adolescent psychiatry. We will also enroll one parent/legal guardian per child subject (N=72 adult subjects). Half of child subjects will be assigned to the experimental Recovery & Care program intervention group and half to active canine-interaction control intervention group.

8.b. Method of subject selection: Subjects will be selected for the study if their parent/legal guardian responds to the recruitment flier and if they meet initial eligibility criteria through the online and phone eligibility screens.

Final eligibility for the study is determined by research project staff based on information obtained from the baseline assessment as well as information obtained from the child's medical record, using the below inclusion/exclusion criteria. Children who are found to be ineligible for the study during the baseline assessment or review of medical records will not be invited to participate in the dog therapy interventions or the follow-up assessment.

8.c. Randomization:
Children will be randomly assigned to either the Recovery & Care dog training intervention or the active canine interaction intervention using a computer-generated, blocked, stratified randomization procedures to balance the two groups proportionally on total sample, gender, and age, thereby reducing bias and confounding that may be attributable to these factors.

8.d. Exclusion/Inclusion criteria:

Individuals who meet the following Inclusion Criteria **MAY** participate in this study:

1. Youth must be between ages 12 years, 0 months to 17 years, 8 months at the time of the baseline assessment.
2. Youth must be receiving outpatient mental health service from the Department of Psychiatry & Behavioral Neuroscience at the University of Chicago.
3. Youth must provide informed assent to participate in the study.
4. Youth must have a parent/legal guardian who can provide informed consent.
5. Families must be available for participation in all 6 intervention weeks, although youth who miss sessions will not be dropped from the study.
6. Youth must complete at least one of the primary outcomes during the baseline

assessment.
7. Youth must attend at least one of the 6 dog therapy intervention sessions.

Individuals who meet the following Exclusion Criteria **MAY NOT** participate in this study:

1. Youth does not provide written assent to participate in study.
2. A parent does not provide written informed consent for youth participation.
3. Youth has a neuropsychological condition/deficit (e.g., severe intellectual disability or developmental delay, severe autism) that would limit comprehension of informed assent documents, comprehension of study materials, or participation in the dog therapy intervention conditions.
4. Youth has a current or past history of major, severe psychiatric disorder (e.g. schizophrenia, bipolar disorder, other psychosis).
5. Youth has major physical limitation that would limit participation in some aspect of the study, including:
    a) Visual impairment that would prevent subjects from being able to see demonstration of intervention activities.
    b) Hearing impairment that would prohibit subjects from understanding intervention directions without an external sign language interpreter.
    c) Upper body mobility restrictions that would prohibit subjects from being able to pet the dog and/or give hand signals to the dog during the intervention. Note that the CTCorps facility is fully ADA compliant and participants with lower body mobility restrictions, including the use of a wheelchair, would still be able to participate.
6. Youth has asthma, a severe animal allergy, or phobia of dogs that would prohibit participation in the intervention.
7. Youth has self-reported history of serious, repeated, developmentally inappropriate maltreatment of animals.
8. Youth who score above the median adjusted t-score on standardized measures of *both* the behavior and emotional regulation subscales of the BRIEF-2 instrument will be excluded in order to minimize potential floor effects (e.g., it will be difficult to show improvements in youth without current deficits in emotion regulation and impulse skills).
9. Youth who score below 60 on the standardized vocabulary and matrix reasoning subscales of the WASI for children will be excluded to ensure the child has the cognitive capacity to provide informed assent and to participate in all study activities.

9. Description of the statistical analysis to which the data will be subjected. This allows the IRB to ensure that study will produce statistically valid conclusions to justify the research on human subjects.

Data analysis for this study will use intent-to-treat methods. *A priori* power calculations for paired t-tests suggest that we will have 80% power to find significant effects in the medium-to-large range, i.e., Cohen's d' = 0.41 to 1.00, which is appropriate for this pilot study of preliminary efficacy.

We will use within-person analyses (paired t-tests) to examine the effects of the intervention on primary outcomes from baseline to follow-up.

We will compare follow-up outcome measures across the two intervention conditions using general linear models.

We will use repeated measures ANOVA to assess the effect of the interventions on short-term mood. We will include intervention condition, time (pre-post) and week (session number) as primary predictors.

We will test for differences in rates of attrition and missed therapy sessions across study conditions using chi-square tests.

10. Potential risks and benefits to subjects.

10.a. Level of Risk: The research activities consist of interactions with therapy dogs, brief interviews, self-report questionnaires, and computerized neuropsychological testing from youth subjects aged 12-17. These activities are non-invasive, safe, and are activities youth could encounter in everyday life. Because of these factors, we believe the study meets the criteria for no more than minimal risk under federal regulation 45 CFR 46.404.

10.b. Potential Risks:

1) Structured interviews. The structured interviews obtaining information on youth demographics, pet and animal exposure, and treatment of animals may be boring to some individuals and may contain certain questions of sensitive nature. All youth in this study will be informed that they are free to refuse to answer any questions.

2) Self-report survey assessments. There are few, if any, risks associated with the self-report assessments. There are no physical risks other than boredom, and self-report questionnaires will be short (< 20 minutes) and youth will be allowed to take breaks. Because survey materials will not contain names or any other identifying information, there is little social or legal risk associated with the self-report questionnaires. There is limited risk of loss of confidentiality, as data will be entered directly into REDCap using a study tablet. All youth in this study will be informed that they are free to refuse to answer any questions.

3) Computer-based behavioral/neuropsychological tasks. There is no physical risk to participating in short computer-based tasks proposed for this study. Computer-based tasks proposed are developmentally appropriate tasks recommended by the NIH (i.e., NIH Toolbox, PhenX project); all tasks are currently being conducted in other large-scale, NIH-funded studies (e.g., the ABCD Study). There is limited risk of loss of confidentiality, as tasks are completed online and data are recorded directly into a secure cloud based platform.

4) Human-Animal Interaction. Any interaction involving a live animal carries some risk of injury (i.e., dog bites, scratches). Procedures for handling these risks are described below.

10.c. Benefits:

This study tests two forms of dog therapy which could have direct impact on child outcomes. Being in this study may help children learn to control their emotions and behaviors and to feel better about themselves.

11. Monitoring of safety of subjects.

11.a. General Protections against Risks.

While NIH has designated this as a clinical trials study, no new drugs or devices will be administered. The two interventions are safe, non-invasive canine-assisted activities that the average child might encounter in daily life.

All interview, survey, and computer-assisted assessments are derived from existing, reliable, and safe measures and tasks that have been used in other studies with children. All data for the study will be entered directly into a private, password-protected database on REDCap. A REDCap ID will be used to link study materials within subjects, and Personal Identifying Information (PII) and Personal Health Information (PHI) from medical records will not be retained. Any adverse events will be immediately reported to both the University of Chicago IRB and to the NIH, following the published guidelines.

11.b. Recovery & Care Canine Therapy Intervention.

The experimental Recovery & Care Canine-Assisted Therapy intervention was developed by the Canine Therapy Corps (CTCorps) and the program has been conducted in hundreds of participants to date, including youth with serious social, emotional, and behavioral problems. The program has been implemented both on- and off-site. While the active canine-interaction control intervention has been developed for this protocol, intervention activities are a blend of activities from the Recovery & Care intervention, as well as from the numerous dog visitation programs that the CTCorps offers. Both interventions will be delivered by trained, CTCorps-affiliated staff and will occur at the CTCorps facility under the supervision of CTCorps-affiliate staff.

Volunteer dog-handler teams who participate in the Recovery & Care program have been comprehensively trained in program activities by the CTCorps. In order to qualify to participate in the Recovery & Care program, all dog-handler teams must successfully pass the Canine Therapy Corps' Therapy Dog Certification test, which is evaluated on a PASS/FAIL basis. This means the Handler and Dog must successfully complete ALL test exercises. Less than 10% of dog-handler teams pass the Certification Test on the 1st attempt, indicating a high standard for behavior.

During the CTCorps' Therapy Dog Certification Test, the dog must be on a flat, buckle collar with a 4' or 6' fixed-length leash. No training aids (e.g., collars, harnesses, food, toys, clickers, etc.) of any sort may be used or on the Handler's person during the Certification Test. Canine Therapy Corps is looking for the Handler to exhibit verbal control over the Dog, meaning the Dog responds to the Handler's verbal instructions - come, sit, stay, heel, down, etc. - within 4 cues, without the necessity of the following to encourage the required behavior: leash pressure; training aids; physical touch or modeling; sounds or vocalizations other than the verbal cue (e.g., finger snapping, clapping, whistling, clicking, kissing, etc.), yelling, scolding, intimidation, or other sounds or body language. Simple obedience hand signals (e.g., hand to heart for "come") are permitted. The Handler must be standing and upright when commanding the Dog during the Certification Test.

In addition to the rigorous training of the dog-handler teams, other safety precautions are in place during each dog therapy intervention session, per current safety procedures used for the existing programming. All dogs will always kept on leash when on-site. The dog handler will be physically present for the entire intervention. Intervention sessions will further be monitored by a

certified canine behavior expert and a clinical supervisor, both of whom are trained by CTCorps. These personnel will monitor for safety and signs of distress in either the dog or the youth participant. Dog-handler teams will be dismissed if the dog demonstrates behavior unbecoming a therapy dog at any point during the intervention session. Behavior unbecoming a therapy dog includes but is not limited to: mouthing of any kind (the leash, a person, etc.), lip lifting/tooth displays; uncontrolled barking or vocalizing; and reactivity or aggression. If necessary, the dog-handler team would be replaced with an alternate for the remainder of the program sessions.

11.c. Data Safety and Monitoring

The intervention and research activities are non-invasive, safe, and consist of activities youth could encounter in everyday life. Because of these factors, Data Safety and Monitoring will occur locally.

The Data Safety and Monitoring Team for this protocol consists of Dr. Jacobson (PI, developmental scientist), Dr. Radwan (Co-I, UC child psychiatrist), and Ms. Cozzolino (External Consultant, former Executive Director of the Canine Therapy Corps, co-developer of the Recovery & Care intervention). Responsibility for oversight of the overall study is provided by the Principal Investigator, Dr. Jacobson.

Because the two dog therapy interventions will be delivered to youth at the Canine Therapy Corps (CTCorps) facility using CTCorps-affiliate staff, the on-site CTCorps Clinical Supervisor will monitor the safety of youth subjects during the intervention. Research staff are on-site during the intervention as observers and to conduct a brief mood questionnaire immediately before and after each intervention program session. Research staff will record potential adverse events and/or study protocol violations as part of the weekly fidelity checklists. Baseline and Follow-up data from youth in both intervention groups will be collected by the Project Manager in the PI's laboratory at the University of Chicago. The Project Manager will record any adverse events or protocol violations that occur during these periods of data collection.

11.d. Monitoring Procedures

The PI will ensure that informed consent and youth assent is obtained prior to performing any research procedures, that all subjects meet eligibility criteria, and that the study is conducted according to the IRB-approved research protocol.

The entire Data and Safety Monitoring team will meet before and after each of the three intervention cohorts. Dr. Jacobson will meet with research staff following the Baseline and Follow-up data collections and after each intervention session to review any potential adverse events or protocol violations that occurred. If a serious protocol violation or adverse event occurs, Dr. Jacobson will convene a meeting of the entire Data Safety & Monitoring team within 48 hours to determine the best course of action.

Study data are accessible at all times the PI to review. Drs. Jacobson (PI) and Radwan (Co-I), along with project research staff, will review study conduct, drop-outs, and protocol deviations on a monthly basis. In the unlikely event of a Serious Adverse Event (SAE), the PI and Co-I will review these SAEs as soon as they occur.

11.e. Collection and Reporting of SAEs and AEs

Standard definitions of AE/SAE are used in this study:

Adverse event (AE). Any unfavorable and unintended sign, symptom, injury, or disease associated with the study activities.

Serious Adverse Event (SAE). Any AE that occurs during the study and results in any of the following:

1. Death
2. Life-threatening outcome
3. Suicidal ideation
4. Substance abuse/overdose
5. Event requiring transport to the Emergency Department
6. Event requiring inpatient hospitalization

Reporting of AEs & SAEs. Any AE or SAE that occurs during the study will be immediately reported to the PI. For possible psychiatric or medical AE/SAE in children, the PI will consult with Dr. Radwan (Co-I) and the onsite Clinical Supervisor to determine the nature and severity of the event. All child-related AE/SAEs will be reported to the University of Chicago Institutional Review within 24 hours, who will determine whether further reporting is needed, following current IRB guidelines.

11.f. Management of Risks to Subjects

Expected AE/SAEs.

There are no expected SAEs for the proposed study. Expected AEs associated with all canine-assisted activities include dog bite, nip, or scratch. If an injury occurs during the course of the intervention, the child will be removed from the intervention room immediately. The on-site CTCorps Clinical Supervisor will examine any dog-related injuries that occur in real-time to determine the severity (mild, moderate, severe) of the injury and will provide direct medical assistance as needed. The CTCorp facility is equipped with appropriate supplies (e.g., antiseptic, bandages, band-aids) to deal with any mild injuries. For any SAE, immediate medical care will be sought via emergency services called on-site or by transporting the child to UCMC. It should be noted that in over 10 years of delivery of the Care & Recovery program to 100s of individuals, given the stringent requirements for certification as a therapy dog, the only reported AEs have been scratches from a therapy dog.

11.g. Data Analysis of Safety

An interim analysis of safety is planned after each intervention cohort has been completed. During this process the PI will review expected AEs in aggregate and any individual SAEs. If the study appears to be inducing undue, persistent levels of stress or injury in either child subjects or therapy dogs, the PI will consult with the IRB and the NIH to determine whether the study should be terminated.

11.h. External Data Safety & Monitoring Board

Because the project does not involve a Phase III clinical trial, an outside Data Safety & Monitoring Board is not required.

12. Payment to subjects.

Youth and adult subjects will be compensated for their time, with separate reimbursement for transportation.

Payments will be made in cash for in-person visits and with gift-cards or mobile cash transfers (e.g., Venmo) for online visits.

The following payment schedule will be used:
- Adult and child subjects will each receive $20 for participating in the baseline assessment at the beginning of the study ($40 total).
- Adults and child subjects will each receive $25 for participating in the follow-up assessment at the end of the study ($50 total).
- Child subjects will receive $30 for each of the 6 dog therapy sessions that they attend.

The maximum total amount of payment that a family will receive for participating in this study is $270.

We will also provide families with a parking voucher for each visit to the University of Chicago. We will give $20 to cover transportation to each dog training session (maximum of $120 for transportation).

13. Procedures to obtain and record informed consent.

Because the study involves participation in intervention activities that are safe, non-invasive, and part of everyday life (interactions with dogs) and data collection using non-invasive interview, survey, and computer-assisted data collection, the study meets criteria for minimal risk and does not require consent by both parents.

Once parents/guardians call or email in response to recruitment materials, the general study will be explained and we will conduct a brief telephone screen to determine eligibility. If eligible, the Project Manager will schedule the family to come into the PI's lab at their convenience, including afternoons, evenings, weekends, and school holidays within a two-week period prior to the start of the intervention.

When the family arrives for the baseline study procedures, the nature of the research project is described in detail to the subjects. A written summary of research procedures, written in lay-person terms that are developmentally-appropriate, is provided to the youth and their parent in the informed consent documents. The consent documents inform the participants of the voluntary nature of the study procedures, and of any potential risks.

Assent is obtained from each child and written informed consent obtained from their parent/legal guardian. Subjects will have the youth assent and parental consent forms read to them by trained project staff as they follow along with an individual copy, and will be asked if they understood what was read to them, and have any questions answered, prior to being asked to sign the respective forms. Youth will be able to ask questions and will be asked to indicate that they understand the study procedures through a brief series of yes/no questions that have been used in the PI's prior research in youth.

Copies of all consent/assent forms are given to the families with contact numbers that would allow youth or their parents/legal guardians to contact project staff to request termination in the study and/or that their data be destroyed. Copies of written consent/assent forms will be retained for at least 5 years in a secure, locked file cabinet stored in the PI's personal, locked office.

All study investigators and research staff interacting with study subjects will have completed NIH Human Subjects Training.

14. Procedures which will be used to maintain confidentiality of research and study subject materials.

Data collected directly from subjects will not include any identifying information. Subjects will be assigned a numeric study ID in the REDCap system. All interview and self-report survey data collected for this study will be entered directly into REDCap using designated, password-protected project tablets. REDCap data are entered via secure online links that are only accessible to the study Investigators and research project staff.

Data collected during the neuropsychological tasks are either stored directly on a secure, centralized data storage cloud or will be entered directly into REDCap. Neuropsychological data will be linked to the youth participant using the study ID.

Data extracted from medical records will be entered into the subject's record on REDCap. Any paper or other electronic copies of the medical chart data will be destroyed immediately after data entry.

All components of the REDCap data system will be accessible only through a login and password unique to each assigned user on the study team. The security access levels for these login accounts will be tiered based on specific roles and responsibilities for the project. The features and privileges associated with each role and subsequent access level will be determined based on the level of access to confidential data needed by each team member. For example, the PI and senior project staff will be the only persons with access to personally identifying and clinical information extracted from medical charts.

All data downloaded for statistical analyses will be stored on secured, password-protected database servers. At the end of the study, all identifying information will be permanently deleted.

15. Bibliographic references to support the hypothesis and the justification for the use of human subjects and in particular the inclusion of any vulnerable populations.

15.a. Review articles on animal assisted activities and/or canine therapy in samples of youth:

Carr S. The attachment-related benefits of animal companions in foster care. International Journal of Birth and Parent Education. 2018;5(2):33-4.

Hoagwood, K.E., et al., Animal-assisted therapies for youth with or at risk for mental health problems: A systematic review. Applied developmental science, 2017. 21(1): p. 1-13.

Jones MG, Rice SM, Cotton SM. Incorporating animal-assisted therapy in mental health treatments for adolescents: A systematic review of canine assisted psychotherapy. PLoS One. 2019 Jan 17;14(1):e0210761. doi: 10.1371/journal.pone.0210761. PMID: 30653587; PMCID: PMC6336278.

Waite, Tabitha C., Lindsay Hamilton, and William O'Brien. "A meta-analysis of animal assisted interventions targeting pain, anxiety and distress in medical settings." Complementary therapies in clinical practice 33 (2018): 49-55.

15.b. Articles on use of animal-assisted therapies/activities in vulnerable youth:

Balluerka, Nekane, Alexander Muela, Nora Amiano, and Miguel A. Caldentey. "Promoting psychosocial adaptation of youths in residential care through animal-assisted psychotherapy." Child abuse & neglect 50 (2015): 193-205.

Carr S, Rockett B. Fostering secure attachment: Experiences of animal companions in the foster home. Attachment & Human Development. 2017 May 4;19(3):259-77.

Downes, Martin J., Ali Lakhani, Annick Maujean, Kym Macfarlane, and Elizabeth Kendall. "Evidence for using farm care practices to improve attachment outcomes in foster children: A systematic review." The British Journal of Social Work 46, no. 5 (2016): 1241-1248.

O'Haire, Marguerite E., Samantha J. McKenzie, Sandra McCune, and Virginia Slaughter. "Effects of classroom animal-assisted activities on social functioning in children with autism spectrum disorder." The journal of alternative and complementary medicine 20, no. 3 (2014): 162-168.

McCullough, Amy, Ashleigh Ruehrdanz, Molly A. Jenkins, Mary Jo Gilmer, Janice Olson, Anjali Pawar, Leslie Holley et al. "Measuring the effects of an animal-assisted intervention for pediatric oncology patients and their parents: A multisite randomized controlled trial." Journal of Pediatric Oncology Nursing 35, no. 3 (2018): 159-177.

16. Description of recruiting methods (i.e., advertisements, patient records, primary physician referrals). If ads are to be used, indicate where ads will be placed and who will handle responses to the ads. In addition, indicate whether patients are being recruited through clinicians or primary physicians.

Subjects in this study will be recruited in the following ways:

a. Fliers will be placed in in hallways and on approved notice boards throughout the UCMC. Families who are interested in the study will contact study staff via phone, email, or QR code and will be screened for eligibility as described in Section 3.g.

b. We will recruit subjects through medical records.

   We are targeting pediatric patients who have received services in relevant clinics and programs in the department, including the: 1) General Pediatric Psychopharmacology Clinic; 2) Pediatric Evaluation and Assessment Clinic, 3) Pediatric Mood & Anxiety Clinic; 4) Pediatric Trauma services (U-STAR and REACT Clinics); 5) and Individual and Group Psychotherapy programs.

   Clinicians overseeing the above clinics have given permission to search medical records for patients who have received care during the past 12 months and/or will be receiving care during the course of the study.

   Children who meet the initial age and diagnostic inclusion/exclusion criteria will be eligible for inclusion. Names of potential patients will be sent to the respective attending clinicians to confirm that the child is a potential candidate for the study. Once confirmation has been obtained, the parent/legal guardian will be sent an IRB-approved recruitment letter and study flier. Clinicians will not be informed whether or not their patients participate in the study.

   Families who respond to the recruitment letter and are interested in the study will contact study staff via phone, email, or QR code and will be screened for eligibility as described in Section 3.g.

17. Description of how the subject's primary physician will be notified of and, as appropriate, involved in the proposed research.

The child subject's primary physician will not be notified of whether or not the child is participating in the proposed research. Research data will not be shared with any UCMC clinicians and will not become part of the child's medical records.

Because Dr. Radwan is a child psychiatrist who treats patients who may be eligible for this study, we will limit access to any patient identifying information in REDCap so he should be unaware of whether or not his patients are participating in this study. The only exception to confidentiality would be if Dr. Radwan needed to be consulted about a clinical concern or a study-related injury that involves one of his patients.

18. Description of anticipated coordination between appropriate inter-departmental faculty, and where necessary inclusion of those faculty as participants.

Not applicable. No inter-departmental coordination is required.

19. If applicable, the protocol should clarify whether subjects will be asked to take a pregnancy test before and, as applicable, during the study.

Not applicable. There are no known risks for pregnant females in any of the study tasks.

20. As applicable, a rationale for excluding women, minorities and/or children from participation.

Not applicable. Eligible children of all gender identities and all from racial/ethnic groups will be included in the proposed research. No exclusions will be made on the basis of gender or race/ethnicity.

21. If applicable, the protocol should state who will infuse the patients with drugs, how it will be done, where it will be done, and what the individual's background and training is.

Not applicable. There is no use of drugs in this study.

22. Citations used in protocol narrative.

1. Cooper, J.L., et al., *Unclaimed children revisited: The status of children's mental health policy in the United States.* 2008.
2. Bora, E., M. Yucel, and N.B. Allen, *Neurobiology of human affiliative behaviour: implications for psychiatric disorders.* Current opinion in psychiatry, 2009. **22**(3): p. 320-325.
3. Sobo, E.J., B. Eng, and N. Kassity-Krich, *Canine visitation (pet) therapy: Pilot data on decreases in child pain perception.* Journal of Holistic Nursing, 2006. **24**(51-57).
4. Kaminski, M., T. Pellino, and J. Wish, *Play and pets: The physical and emotional impact of child-life and pet therapy on hospitalized children.* Childrens Health Care, 2002. **31**(4): p. 321.
5. Tsai, C.C., Friedmann, E., & Thomas, S. A. , *The effect of animal-assisted therapy on stress responses in hospitalized children.* Anthrozoos, 2010. **23**(3): p. 245-258.
6. Braun, C., Stangler, T., Narveson, J., & Pettingell, S. , *Animal-assisted therapy as a pain relief intervention for children.* Complementary Therapies in Clinical Practice, 2009. **15**(2): p. 657-670.
7. Hergovich, A., et al., *The effects of the presence of a dog in the classroom.* Anthrozoos, 2002. **15**(1): p. 37-50.
8. Tissen, I., A. Hergovich, and C. Spiel, *School-based social training with and without dogs: Evaluation of their effectiveness.* Anthrozoos, 2007. **20**(4): p. 365-373.
9. Crossman, M., *Effects of interactions with animals on human psychological distress.* Journal of Clinical Psychology, 2016. **73**(7): p. 761-784.
10. Oetzel, K.B., & Scherer, D.G., *Therapeutic engagement with adolescents in psychiatry.* Psychotherapy: Theory, Research, Practice, Training, 2003. **40**(3): p. 215-225.
11. Herzog, H., *The research challenge: Threats to the validity of animal-assisted therapy studies and suggestions for improvement.* , in *Handbook on animal-assisted therapy: Foundations and guidelines for animal assisted interventions*, A.H. Fine, Editor. 2015, Elsevier: Waltham, MA. p. 402-407.
12. Kazdin, A.E., *Establishing the effectiveness of animal-assisted therapies: Methodological standards, issues, and strategies*, in *How Animals Affect Us: Examining the Influence of Human-Animal Interaction on Child Development and Human Health*, P. McCardle, et al., Editors. 2010, American Psychological Association: Washington, D. C. p. 35-51.
13. Esposito, L., et al., *Directions in human-animal interaction research: Child development, health, and therapeutic interventions.* Child Development Perspectives, 2011. .
14. Tedeschi, P., et al., *Treating human trauma with the help of animals: Trauma informed intervention for child maltreatment and adult post-traumatic stress*, in *Handbook on animal-assisted therapy*. 2015, Elsevier. p. 305-319.
15. Chandler, C.K., *Animal-assisted therapy in counseling*. 2017: Routledge.
16. Collis, G.M. and J. McNicholas, *A theoretical basis for health benefits of pet ownership*, in *Companion Animals in Human Health*, C.C. Wilson and D.C. Turner, Editors. 1998, Sage Publications, Inc.: Thousand Oaks, CA. p. 105-122.
17. Reichert, E., L. Bermel, and C.F. Sori, *Animal-assisted therapy for sexually abused children.* The therapist's notebook for children and adolescents: Homework, handouts, and activities for use in psychotherapy (2nd ed., pp. 125–130). Routledge, 2016.
18. Allen, K.M., et al., *Presence of human friends and pet dogs as moderators of autonomic responses to stress in women.* Journal of Personality and Social Psychology, 1991. **61**(4): p. 582-589.
19. Polheber, J.P. and R.L. Matchock, *The presence of a dog attenuates cortisol and heart rate in the Trier Social Stress Test compared to human friends.* Journal of Behavioral Medicine, 2014. **37**(5): p. 860-867.

20. Katcher, A.H. and G.G. Wilkins, *Animal-assisted therapy in the treatment of disruptive behavior disorders in children*, in *The Environment and Mental Health: A Guide for Clinicians* A. Lundberg, Editor. 1998, Lawrence Erlbaum: Mahwah, NJ. p. 193-204.
21. Winnicott, D.W., *Transitional objects and transitional phenomena*, in *Essential Papers on Object Relations* P. Buckley, Editor. 1986, New York University Press: New York. p. 254-271.
22. George, H., *Child therapy in animals*, in *Innovative Interventions in Child and Adolescent Therapy*, C.E. Schaefer, Editor. 1998, John Wiley: New York. p. 400-418.
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24. Cutt, H., et al., *Dog ownership, health and physical activity: A critical review of the literature.* Health & Place, 2007. **13**(1): p. 261-272.
25. Garrity, T.F., et al., *Pet ownership and attachment as supportive factors in the health of the elderly.* Anthrozoos, 1989. **3**: p. 35-44.
26. Hoagwood, K.E., et al., *Animal-assisted therapies for youth with or at risk for mental health problems: A systematic review.* Applied developmental science, 2017. **21**(1): p. 1-13.
27. Kelly, M.A. and C.A. Cozzolino, *Helping at-risk youth overcome trauma and substance abuse through animal-assisted therapy.* Contemporary Justice Review, 2015. **18**(4): p. 421-434.
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29. Celio, C.I., J. Durlak, and A. Dymnicki, *A meta-analysis of the impact of service-learning on students.* Journal of Experiential Education, 2011. **34**(2): p. 164-181.