

## **Cover Page**

**Official Title:** Integrating Animal-Assisted Therapy Into Trauma-Focused Cognitive-Behavioral Therapy for Maltreated Youth (TF-CBT+AAT)

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# Integrating Animal-Assisted Therapy Into Trauma-Focused Cognitive-Behavioral Therapy for Maltreated Youth (TF-CBT+AAT) Protocol

## 1.0 Inclusion and Exclusion Criteria

### 1.1 Inclusion Criteria

#### Minor Patients

- Age 6-17 years (inclusive) with a participating consenting caregiver with legal standing to consent for the minor child (either biological parent or adoptive parent). All youth will be asked to provide assent.
- Sex: male or female
- Fluent in written and spoken English, as the assessment instruments are not available in translations and have not been validated for use with non-English speaking populations.
- An allegation of abuse or neglect investigated by law enforcement or child protective services.
- A raw score of  $\geq 39$  on the caregiver-report version of the UCLA PTSD Reaction Index completed by the caregiver upon presentation to the TLC Clinic or the Pinnacle Health Children's Resource Center (CRC).
- A full scale IQ score of  $\geq 80$  on the Kaufman Brief Intelligence Test (2nd ed.; KBIT-2)

#### Adult Caregiver

- Biological or adoptive parent of a child meeting inclusion criteria. Must consent to his/her own participation as well as the participation of the child.
- Self-identified as the primary caregiver (responsible for the day-to-day care of the child).
- Age  $\geq 18$  years
- Sex: male or female
- Fluent in written and spoken English. See rationale above regarding measures.

NOTE: Only youth were enrolled and only data pertaining to youth functioning was collected. However, given the importance of caregiver report for assessing these outcomes, inclusion and exclusion criteria related to the caregivers was included.

## 1.2 Exclusion Criteria

### Minor Patients

- Age <6 or >18 years
- 6-18 years of age and unwilling to give assent
- A diagnosed cognitive or intellectual deficit, or developmental delay
- An IQ score < 80 on the KBIT-2
- A reported fear of dogs, dog allergy, or prior history of aggression toward animals.

### Adult Caregiver

- Age < 18 years at the time of enrollment
- Caregiver inability to participate in treatment or to complete assessment measures due to cognitive, psychiatric, or other limitation.
- Suspected or known to have perpetrated a form of child maltreatment.
- A reported fear of dogs, dog allergy, or prior history of aggression toward animals

## 2.0 Recruitment Methods

### 2.1 Identification of subjects

Participants will be recruited through two mechanisms. First, children presenting for services at the Penn State Children's Hospital's Stine Foundation Transforming the Lives of Children (TLC) Clinic will be eligible for inclusion. The TLC Clinic exclusively serves maltreated children and, as a condition of admission, an investigated allegation of child maltreatment is required. Children meeting inclusion criteria following their initial assessment at the TLC Clinic will be offered participation in the trial.

Second, children presenting to the Pinnacle Health Children's Resource Center (CRC) for forensic interviews following allegations of maltreatment will be referred to the HMC research team. CRC involvement is limited to providing the attached recruitment letter to the parent of the child who may be eligible for this research.

NOTE: Only youth were enrolled and only data pertaining to youth functioning was collected. However, given the importance of caregiver report for assessing these outcomes, inclusion and exclusion criteria related to the caregivers was included. In addition, caregivers provided consent for the participation of the youth in the study.

## **2.2 Recruitment process**

Potential participants will be referred to study coordinators who will conduct a phone screen for eligibility related to the inclusion of the dogs, explain the study procedures and review inclusion/exclusion criteria. Pending meeting inclusion/exclusion criteria, those interested in participating will be scheduled an assessment session.

## **2.3 Recruitment materials**

The attached recruitment letter will be distributed to potential participants at the time they are identified as meeting initial eligibility at presentation to either the TLC Clinic or CRC.

## **2.4 Eligibility/screening of subjects**

Once participants are contacted by study coordinators, a brief screening questionnaire will be administered over the phone (see attached). Participants who agree to participate will be scheduled for the pre-treatment assessment session where the KBIT-2 and other study measures will be implemented. Final eligibility will be determined after this session.

# **3.0 Consent Process and Documentation**

## **3.1 Consent Process**

### **3.1.1 Obtaining Informed Consent**

#### **3.1.1.1 Timing and Location of Consent**

Child will attend study assessment and treatment appointments at the TLC Clinic (2626 N. 3rd St., Harrisburg). The research assistant will obtain informed consent in a private setting/room

within the clinic when they attend the pre-treatment assessment session.

### **3.1.1.2 Coercion or Undue Influence during Consent**

Study procedures will be fully explained, voluntariness will be emphasized as well as the fact that declining participation will in no way impact the relationship of the participant with the TLC Clinic, Department of Pediatrics, or PSHMC.

### **3.1.2 Waiver or alteration of the informed consent requirement**

Waiver; recruitment of children.

A waiver of consent is requested to review medical record information to determine preliminary eligibility to participate in the research.

## **3.2 Consent Documentation**

### **3.2.1 Written Documentation of Consent**

The consent process will be documented in writing with the long form of consent documentation. The research assistant will assist in the explanation and obtaining of the written consent. A copy of the signed consent will be given to the participant and another copy will be saved in filing cabinets located at the TLC Clinic.

### **3.2.2 Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)**

A waiver of documentation of consent is requested for recruitment purposes because patients interested in the study will be calling the research assistant for a phone screening in response to seeing the recruitment letter or talking to staff at the CRC or TLC Clinic.

Verbal consent will be obtained from study therapists and dog handlers. A summary explanation of the research procedures will be provided to therapists and handlers about their role in completing the study. Verbal consent is used in this case as no PHI is collected from therapists or handlers.

### **3.3 Consent – Other Considerations**

#### **3.3.1 Non-English Speaking Subjects**

N/A: Excluded since the assessment materials used in the current study are only available in English, and have not been validated in other languages.

#### **3.3.2 Cognitively Impaired Adults**

##### **3.3.2.1 Capability of Providing Consent**

Caregivers with obvious cognitive, psychiatric, or other impairment that are incapable of understanding the purpose of the measures or participate in treatment will not be allowed to consent for themselves or their child.

##### **3.3.2.2 Adults Unable To Consent**

Adults unable to provide consent, and their children, will not be enrolled in this study. There would be concerns regarding their ability to provide informed consent and participate in treatment.

##### **3.3.2.3 Assent of Adults Unable to Consent**

N/A

#### **3.3.3 Subjects who are not yet adults (infants, children, teenagers)**

##### **3.3.3.1 Parental Permission**

All children in the study will be between the ages of 6 and 17 (inclusive). Each child will require the consent of a legal caregiver.

This will be obtained when they attend the scheduled pre-treatment assessment session at the TLC Clinic.

##### **3.3.3.2 Assent of subjects who are not yet adults**

Assent will be obtained from all youth participants and documented for all minors 7 years of age or older.

## 4.0 Study Design and Procedures

### 4.1 Study Design

Randomized clinical trial with two active conditions and no placebo or waitlist conditions.

### 4.2 Study Procedures

Children enrolled in the study will already demonstrate a sufficient elevation on the UCLA prior to completing the pre-treatment assessment, either at the TLC Clinic or the CRC. Additional measures (see below) will be completed at a pre-treatment session administered by the research assistant. Children will be randomly assigned to either the TF-CBT or TF-CBT+AAT condition using a blocked randomization procedure to balance the two groups on gender and age, thereby reducing bias and confounding that may be attributable to these factors (Efird, 2011). This randomization will be performed using a computer algorithm in SAS v. 9.4 with randomly selected block sizes of 4, 6, and 8. In addition, each child will be randomly assigned to one of two clinicians participating in the RCT using a random number generator. The randomization sequence will be defined prior to beginning the trial and will be developed and maintained by Dr. Ming Wang (PSU Public Health Sciences). Children will be scheduled to complete a post-treatment assessment within 2 weeks of completing the 12th (final) session of the treatment protocol. The research assistant will administer the posttreatment assessment (measures described below) and all data collected will be entered into a database developed for this project using the Penn State College of Medicine's Research Electronic Data Capture (REDCap) system. Data monitoring and management, and statistical consultation, will be provided by Dr. Wang. The study will be single-blinded as all staff handling data will be blinded to a child's treatment condition (i.e., research assistants, Dr. Wang, Dr. Shenk). The study coordinator/research assistant will be responsible for reviewing study procedures with potential participants, liaising with the CRC, scheduling and verifying appointment times, conducting assessments, and contacting participants to re-schedule in the event that assessment sessions are missed.

The same two clinicians will implement the treatment in both conditions, thereby eliminating the impact of clinician-related factors on outcome. Both clinicians involved in the current project have completed requisite training and supervision requirements set forth by the TF-CBT developers and are certified TF-CBT clinicians. Clinicians will be required to complete and maintain a fidelity checklist (adapted from Deblinger et al., 2014; see attached) and the clinicians themselves will enter this data into REDCap to

ensure the research assistant remains blinded to participant condition. Dr. Allen will facilitate bi-weekly group TF-CBT supervision with the clinicians and be responsible for supervising research assistants.

The clinicians will be responsible for scheduling treatment sessions, which will occur once per week. This project will employ the standard TF-CBT treatment protocol, which includes twelve 90-minute sessions. TF-CBT is typically described as including 3 phases, each focusing on a common goal and encompassing a third of treatment (4 sessions). The first phase focuses on skills-building and includes psychoeducation, parenting skills training, relaxation skills training, affect modulation skills training, and cognitive coping skills training. The second phase involves focused gradual exposure activities, including construction of a narrative account of the child's maltreatment experiences and cognitive processing of maladaptive thoughts. The third phase emphasizes the child's mastery over environmental reminders of the maltreatment and includes sharing the trauma narrative with the caregiver, in vivo exposure to physical stimuli, and enhancing future development.

Susquehanna Service Dogs (SSD), a fully accredited member of Assistance Dogs International (ADI), will partner in the completion of this project (see letter of support from Pamela Foreman). SSD facility dogs are fully trained/certified according to ADI standards and serve in canine-assisted interventions in local mental health settings. These dogs are skilled in basic obedience, maintain a calm manner and good social behavior in a variety of environments, and are trained for public access (<http://www.assistancedogsinternational.org/standards/assistance-dogs/standards-for-dogs/training-standards-for-facility-dogs/>). Three pre-determined facility dog/handler teams will participate in this project. Each team will schedule 4-hour blocks of time either in the morning or afternoon on various days of the week. Children assigned to the TF-CBT+AAT condition will be scheduled in one of these time blocks. The dog will then be considered an extension of the clinician; if the dog cannot attend an appointment then the appointment will be re-scheduled. This will assure that the child remains with the same dog each session for the duration of the protocol. Dogs will only be scheduled to participate with one child per day. If the child needs to change the regular appointment time, the dog's handler will be consulted and attempts will be made to re-schedule without changing the dog involved.

Having the dog's handler in the treatment room for the TF-CBT+AAT condition creates a significant confound as a second individual will not be present in the TF-CBT condition. Therefore, SSD handlers will deliver a 3-hour training to the clinicians in the management of the service dog and provide a further 7 hours of consultation to the clinicians throughout the project. When the session is ready to begin, the handler will transfer the handling duties to the clinician. Handlers will observe sessions through a



one-way mirror and/or closed circuit television system with a focus on monitoring the well-being of the dog. Handlers will be free to interrupt sessions if they believe it is warranted given the dog's behavior. Handlers will not be able to hear what is being discussed from the observation room, although various emotional responses will be visible and they may become aware of some details of the child's maltreatment. The clinicians will provide a 3-hour training to the handlers on secondary trauma and self-care, and provide continuing support to the handlers as needed.

Treatment sessions will be structured as follows: (1) A research assistant will facilitate the application of

electrodes to the child for purposes of recording psychophysiological data (see below). Research assistants will be trained to affix these electrodes by Dr. Shenk. The dog's handler will affix a heart rate monitor to the dog as well as collect a saliva sample for cortisol analysis (see below; IACUC approval pending). Dr. Dreschel will train handlers in these procedures. Note data collection related to the dog is being performed by the handler in order to maintain the blinded status of the research assistant. (2) The child will be given 10 minutes of unstructured time prior to the implementation of treatment techniques to engage in relaxing, pleasurable activities while in the treatment room. Children in the TF-CBT group may select toys, games, books, or other activities, and children will be allowed to determine whether the clinician is involved in these activities. Children in the TF-CBT+AAT group will be given the same options; however, the dog will be in the room during these 10 minutes and the child may interact with the dog during that time. (3) The clinician will implement the child-focused TF-CBT components indicated for the given session (approximately 45 minutes). For the TF-CBT+AAT sessions, the dog will be instructed to sit or lay near the seated child during this time and the child will be allowed to pet or otherwise interact with the dog during the session. Children assigned to the TF-CBT group will be given the option of taking a stuffed animal or other tactile sensory stimulus (e.g., Koosh ball) into session. (4) The dog will be reunited with the handler, and the handler will remove the heart rate monitor from the dog and collect a saliva sample. Children in the TF-CBT+AAT group will be allowed to say good-bye to the dog. A research assistant then will facilitate the removal of electrodes from the child. (5) The clinician will implement the caregiver-focused TF-CBT components assigned for the given session (approximately 45 minutes) and a research assistant will implement indicated data collection procedures with the child (see below). The conditions specified in point (3) will apply during conjoint sessions where both the child and caregiver are present.

## **Measures**

**(1) Posttraumatic stress (PTS)** will be assessed primarily through caregiver-report on the UCLA PTSD Reaction Index. In addition to the pre-treatment/referral and post-treatment assessments discussed above, the caregiver will complete the UCLA when presenting for the 5th treatment session (score after the first phase of treatment [sessions 1-4]) and the 9th treatment session (score after the second phase of treatment [sessions 5-8]). Thus, PTS will be assessed at four separate points in the treatment process, which will allow for a comparison of the rate of progress across the two conditions. Children will also complete the self-report version of the UCLA at each of the four assessment points. **(2) Emotional and behavioral concerns** will be assessed by caregiver-report using the Strengths and Difficulties

Questionnaire (SDQ; Goodman, 1997). As with the UCLA, the caregiver will complete the SDQ at pretreatment, during sessions 5 and 9, and at post-treatment. Children will self-report their anxiety concerns on the Screen for Child Anxiety Related Disorders (SCARED; Birmaher et al., 1999) and their depression concerns on the Mood and Feelings Questionnaire (MFQ; Angold et al., 1995) at each of the four assessment points. A research assistant will be responsible for administering measures at each assessment.

**(3) Emotion regulation** will be assessed in three ways. First, caregivers will complete the Emotion Regulation Checklist (ERC; Shields & Cicchetti, 1997) during the pre- and post-treatment assessments. Similarly, children will complete the self-report Emotion Regulation Index for Children and Adolescents (ERICA; MacDermott et al., 2010) during the pre- and post-assessments. Last, children's resting and stress reactivity respiratory sinus arrhythmia (RSA) will be assessed both pre- and post-treatment. RSA is assessed via an electrocardiogram (ECG) and is a well-established psychophysiological marker of emotion regulation (Beauchaine, 2015). RSA will be assessed with a UFI 3991/4 EIRS BioLog ambulatory physiological data recorder using disposable Ag/AgCl electrodes. Electrodes will be placed on the chest and abdomen to acquire inter-beat intervals. Placement of the electrodes will be facilitated by the research assistant conducting the assessment and the child's caregiver will be present during the application and later removal of the electrodes. The caregiver will not be present during the administration of the assessment procedures. To assess resting RSA, children will watch pre-selected television programs that are not emotionally-laden for 15 minutes. Stress reactivity will then be assessed using the Trier Social Stress Test (TSST; Buske-Kirschbaum et al., 1997; Kirschbaum et al., 1993). In addition, children will be shown a \$15 gift card to a toy or electronics store prior to beginning the TSST and told that they must achieve a satisfactory performance across the TSST tasks to earn the gift card. The gift card will be provided to all participants at the completion of the TSST. In both the resting and stressor paradigms, RSA will be sampled in 30 second epochs. Dr. Shenk, who will be blind to participant condition, will be responsible for editing the ECG files to remove artifacts and scoring the files using CardioEdit and CardioBatch software (Brain-Body Center, University of Illinois at Chicago, 2007). Dr. Shenk is trained and certified by the developers in the use of this software. **(4) Youth perception of the caregiver** will be assessed at both the pre-treatment and post-treatment assessment sessions using the Security Scale, to determine whether participation in TF-CBT improved the youth's perception of their caregiver as a source of support. To examine potential caregiver-

related interpersonal factors on this outcome, the caregiver will complete the Experiences in Close Relationship-Revised (ECR-R) and the Caregiving Systems Scale (CSS).

**(5) Participant attrition, cancelled appointments, and missed appointments without prior notice** will be recorded to determine if the conditions differ on consistency of attending and completing treatment. **(6) Treatment satisfaction** will be assessed by caregiver and child report during the posttreatment assessment using the Youth Client Satisfaction Questionnaire (YCSQ; Shapiro et al., 1997). **(7) Ability to implement TF-CBT techniques** will be assessed in multiple ways. First, the number of sessions that are cancelled because of reasons attributable to the availability of the dog will be recorded (e.g., dog/handler illness). Second, the clinician will complete a fidelity checklist after each session to report whether the assigned techniques for the session were successfully completed (see attached). Completing such checklists will allow for a comparison between the two conditions to determine whether the presence of the dogs facilitated a greater rate of completion of assigned techniques or hindered completion of assigned techniques. Third, clinicians will report whether a treatment disrupting event attributable to the dog occurred during session (e.g., emotional distress requiring handler intervention). **(8) Stress response in dogs** will be evaluated using physiological and behavioral measures. To measure hypothalamic-pituitary-adrenal (HPA) response, three saliva samples for cortisol assessment (pre-session/prior to meeting child, post-session/immediately after separation from child, and 20 minutes post-session) will be taken from each dog at treatment sessions 1, 6, and 12 (beginning of treatment protocol, predicted child peak emotional level during protocol, end of treatment protocol). Each of these samples will be obtained by the handler. Representative control day samples (at the same time on non-therapy days) will be taken by the handler at home for each dog. Dr. Dreschel will train handlers in the collection, transportation, and storage of samples. For autonomic nervous system response, canine heart rate will be measured at each session using a Polar H7 monitor with bluetooth connection to a tablet computer. Using conversion software, RSA (R-R intervals) will be determined for each session. Sessions will be videotaped and Dr. Dreschel will code behavioral stress signals in the dogs as well as children's behavior toward the dogs (Dreschel & Granger, 2005). In addition, handlers will be trained by Dr. Dreschel to assess their dogs' behavior before, during, and after treatment sessions using the Behavioral Instrument for the Assessment of Dog Well-Being Before/During/After Therapy Sessions (Fine, et al., 2013; Ng et al., 2015).

**(9) Stress experienced in session** will be assessed via ECG. Children will be connected to a UFI 3991/4 EIRS BioLog ambulatory physiological data recorder using disposable Ag/AgCl electrodes prior to the start of treatment sessions 1, 4, 6, 8, and 12. Placement of electrodes will be performed by a research assistant using the procedures specified previously. Event marks will be recorded at the point of transition from the 10-minute

relaxation/pleasurable activities time to the start of the implementation of techniques. RSA will be sampled in 30 second epochs and calculated for each of these two time periods (10 minute phase prior to technique implementation, 45 minute phase of technique implementation). This methodology will allow for assessment of within-participant RSA trajectories over the course of treatment, and between-group comparisons on physiological stress response both prior to and during technique implementation. **(10) Quality of therapeutic rapport** will be assessed via child and caregiver-report using the appropriate versions of the Therapeutic Alliance Scale for Children-Revised (TASC-R; Accurso et al., 2013; Creed & Kendall, 2005; Shirk & Saiz, 1992). AAT is believed to facilitate the development of rapport and, therefore, assessing rapport at multiple points in the first phase of treatment is appropriate. As such, rapport will be assessed at the 2nd and 4th treatment sessions as well as at post-treatment. A research assistant will administer the TASC-R with caregivers and children during these sessions and will explicitly state that the clinician will not be made aware of the answers provided. **(11) Attitudes toward pets** will be assessed for the youth at the pre-treatment assessment only using the Pet Attitude Scale to determine whether pre-existing attitudes toward pets is related to outcome in the TF-CBT+AAT group. **(12) The demographics** form will be completed at the pre-treatment assessment only.

**Note on the Recording of sessions:** The TLC Clinic currently has video recording capabilities and uses them on a regular basis. These recording are done by equipment installed in the TLC Clinic by the PSHMC IT department and stored digitally on PSHMC servers behind the firewall. A back-up system uses a camcorder within the clinic and the files are stored on a memory card. The files are then transferred to the TLC Clinic shared drive that is only accessible to TLC Clinic staff with permission to access the drive. The video recorded files are then deleted from the memory card.

#### **4.3 Duration of Participation**

Each child is expected to participate in the pre-treatment assessment, 12 sessions of treatment, and a post-treatment assessment.

## **Statistical Plan**

#### **5.1 Number of Subjects**

60 participant youth

#### **5.2 Sample size determination**

Although a primary objective of this study is to derive effect size estimates that can inform the design of a larger clinical trial, a preliminary power analysis was conducted. Results indicated that the proposed sample of 60 participants (equal sample sizes across the two conditions) can achieve 80% power to detect an approximately 5 point difference of pre-post change between the groups on the PTS measure (i.e., UCLA) when the standard deviation of each group is assumed to be 6.5 and the significance level is set at .05. Ethnic and gender composition will likely reflect those of the larger Harrisburg area (45% White, 45% African-American, 10% other ethnicities; 50% female, 50% male).

## 5.2 Statistical methods

Intent-to-treat analyses will be used for all statistical analyses (i.e., all of the available data from randomized participants are utilized for analyses). Descriptive statistics (e.g., means, ranges, standard deviations) will be computed for continuous variables; frequencies will be calculated for

categorical variables. Measurements of PTS, emotional and behavioral concerns, and emotion regulation are continuous variables and will be examined over time with individual-level graphical checks. Transformation methods may be needed based on normality checks (i.e., Shapiro-Wilks test). To adjust for potential confounding variables that may be identified (e.g., gender, age, number of trauma types endorsed on the UCLA), multilevel models with partial nesting (i.e., youth in the TF-CBT+AAT group nested by dog, youth in the TF-CBT group not nested) will be employed to investigate the temporal trend and compare the trajectories of outcomes between the two groups using SAS PROC NL MIXED v. 9.4. Note that parameter estimates will be obtained using maximum likelihood estimation, and that p-values can be computed based on Chi-square tests (Liang & Zeger, 1986). If missing data or dropouts occur, the mechanism (i.e., missing completely at random, missing at random) will be explored and adjusted for valid statistical inference.

Analyses of categorical data (i.e., participant attrition, cancelled appointments, missed appointments without prior notice, and ability to implement TF-CBT techniques) will likely utilize descriptive and non-parametric methods (e.g., Fisher's exact tests). Differences between the conditions for treatment satisfaction will be examined with parametric (e.g., between groups t-tests) or non-parametric

analyses (Wilcoxon rank-sum tests). Given the small sample sizes and primary interest in a covariate effect, generalized estimating equations (GEE) can be used for the analysis of repeated cortisol assessments (Wang & Long, 2011). The GEE model with autoregressive (AR) working correlation structure can be fitted to investigate the difference of within session samples and between the treatment and control day samples. Three variables of interest are included: day of sample (0 = control; 1 = treatment), the session status (0 = pre-session; 1 = post-session; 2 = 20 minutes post-session), and their interaction.

Modified variance estimators are calculated to reduce bias when sample sizes are small and t-tests are used for valid inference. The analysis will be conducted using the function of “geesmv” in R (Wang et al. 2016). Similar methods can be used for the analysis of canine heart rate variability and behavior.

With regards to the ECG data, interrupted time series analyses can be used to analyze RSA from two time periods. The covariates of interest include time (in minutes) since the start of RSA assessment, the treatment group (0 = TF-CBT; 1 = TF-CBT+AAT), the time period (0 = phase prior to

technique implementation; 1 = technique implementation), time (in minutes) since technique implementation, and the interactions of the last variables with the treatment group. The correlation among time series observations is represented in the error term. Residual plots can be used to detect the autocorrelation, where the Durbin–Watson statistic can be used. This model can be fitted by SAS PROC AUTOREG v. 9.4. Regression-based mediational analyses can be conducted at each of the four assessment sessions to examine if therapeutic rapport mediates the relationship between the presence of the dogs and PTS outcomes. Bootstrap or Monte Carlo methods can be applied to testing significance of the indirect effect (Tofighi & MacKinnon, 2015). This model can be fitted using the PROCESS macro for SAS v. 9.4 (Hayes, 2013).