Cover Page for Clinical Trial Study

Official Title: Comparing the Effects of a Plush Toy Dog versus a Live Therapy Canine on Prosocial Behavior and Emotional Regulation in Children with Autism Spectrum Disorder

NCT#: N/A

Date: March 13, 2025

Study Protocol

Clinical Study Description

The purpose of this project is to investigate the human-animal interaction (HAI) and bond (HAB) between a canine trained in therapy techniques or a canine plush toy and youth with autism spectrum disorder (ASD) during animal-assisted therapy (AAT) sessions. We seek to explore identified gaps in knowledge pertaining to AAT in pediatric ASD care management. Specifically, we want to document human interaction between either a live canine or the plush toy canine during AAT sessions, evaluating behaviors observed during and after AAT sessions. Caregivers were given the option to enroll the child in the AAT study at the follow-up appointment after the diagnostic assessment was completed, or upon enrollment in the ASD program if the child had an ASD diagnosis. The study was conducted between June 2022 through August 2024. Each AAT study lasted between eight to 12 weeks, and caregivers had the option to re-enroll the child for the next study to continue addressing behavioral concerns. Participants were divided into two groups: one with a therapy canine and one with a plush toy dog. Therapy sessions lasted 30 to 45 minutes, depending on the age and ability of the participant. All participants, no matter their group, received the same therapeutic strategies, such as sensory integration therapy and seated activity with the therapist, who is a certified pediatric nurse practitioner. Sessions with the therapy canine started with five to 10 minutes of free play with the canine, followed by sensory integration therapy based on the child's identified sensory profile. Participants then entered the clinic room for 20 to 30 minutes of a seated activity in which the therapist who taught coping and socialization strategies to participants and caregivers. Sessions concluded with five minutes of play with the canine. Play activities include fetch, soccer, hide and seek, and puzzles. The canine was trained to lay under the table in the clinic room while the therapist was working with the participants. He would provide grounding, light pressure, and deep pressure therapy if the participant became anxious during the sessions. The seated work was recorded using two cameras to ensure visibility of the interactions between the participant and therapist, canine, and caregiver; participant vocalizations and verbalizations; and participant facial expressions. We used two human-animal ethograms to code behavior during sessions and two behavioral assessments to note behavior occurring after sessions. All sessions occurred in the clinic located on the university's campus. Demographic data including participant age, gender, race, ethnicity, referral source, prior medical diagnoses, age of ASD diagnosis, medications, and prior allied health, school, or psychological evaluations. The canine was certified as a therapy dog and service dog certified in 10 ASD service dog tasks at the time of the study. The canine was present during sessions to interact with children and assist them to practice and develop skills to address identified deficits in social-emotional and adaptive functioning, prosocial behavior, and emotional regulation. AAT sessions were recorded to code interactions at a later time.

Objectives

This study will address the following research questions:

1. How do children with autism ages 2 to 18 years interact with a live canine during AAT sessions?

2. How do children with autism ages 2 to 18 years interact with a toy plush dog during AAT sessions?

3. Is there a difference in HAI in the live canine group and the toy plush dog group?

4. Is there a difference in prosocial behavior observed during AAT sessions between the live canine group and the toy plush dog group?

5. Is there a difference in behavior after AAT sessions between the live canine group and the toy plush dog group?

Design and Statistical Analysis Plan

We used two human-animal ethograms to investigate human-animal interaction and bonding occurring during AAT sessions. Prosocial behavior and emotional regulation demonstrated by participants outside of AAT sessions were assessed by two self-report questionnaires completed by caregivers. SPSS and Microsoft Excel were used to calculate the analysis. Descriptive statistics were utilized to compare prosocial behavior and emotional regulation occurring apart from AAT sessions between the two groups. Poisson analysis was conducted to examine human-animal bonding and human behavior occurring during AAT sessions. Independent t-tests were used to analyze the differences in human-animal interaction between the two groups. The homogeneity of the variance (HOV) assumption between two groups was checked using Levene's test for equality of variances in SPSS program before conducting the t-tests analysis. Results of t-tests with adjusted degrees of freedom value were reported if the HOV was violated. The null hypothesis was set to reflect no significant difference in HAI between groups for the independent t-tests; therefore, a significant difference in the human-animal interaction and human behaviors regarding the inclusion or exclusion of the canine could be confirmed if the t-test results reject the null hypothesis. Cohen's d was used to report the effect sizes of the independent t-tests; values up to 0.20 were interpreted as small, 0.50 as medium, and 0.80 as large effect sizes. Analysis of variance was used to assess differences between the two groups in prosocial behavior and emotional regulation occurring apart from AAT sessions.

Methods

Demographic data; past, family, and social histories; and prior therapy evaluations were collected during the initial consultation for enrollment into the ASD program. Additionally, pet ownership in the family home was included in the analysis.

The Observation for Human Canine Interaction for Research (OHAIRE) Coding System from University of Arizona was used to note human bonding and prosocial behavior occurring during AAT sessions. The OHAIRE Coding System was specifically created for use in research with participants aged 4 to 16 years but may also be suitable for individuals of other ages, provided appropriate validity and reliability analyses are conducted. Participants must be with at least one

other person during sessions to allow for the coding of social behaviors. The participant being observed is known as the primary participant. The coding system allows for the primary participant to engage in social behaviors with various targets, including caregivers, therapists, objects, and canines. While the OHAIRE was designed to code behavior in the presence of common domesticated canine species, it has been tested with a restricted range of canine species to date. The tool has previously been used to code interactions with dogs and guinea pigs, as well as social behaviors before and after interactions with horses (not direct interactions with horses). The coded behaviors are general enough to be assumed to apply to other domesticated canine species. Participants were video recorded continuously during unstructured interaction opportunities. Available activities provided opportunities to engage in both social and isolated behaviors. The video sample included a wide enough angle to observe the environment and all potential social interaction partners. The OHAIRE-V3 calculates a human-canine bond score in order to quantify the interactions taking place between the primary participant and the canine. The human-canine bond score was calculated for each 10-second interval based on the presence of an interaction between the primary participant and the canine, and the type of behaviors shown during that interaction. Participants received one point for each of the six behaviors from the 'social communication & interaction' category in the OHAIRE tool. No points were given if the primary participant does not interact with the canine. The behaviors included in the definition of the human canine bond score are talk, gesture, look, touch, affection, and prosocial behavior directed toward the canine. There are a total of six 10-second intervals within each 1-minute video segment, and each of those 10-second intervals has six possible points: one point for each type of interaction. The total score from each 10-second interval is summed for a total overall human-canine bond score across the entire 1-minute video segment. Each 10-second interval will have a score between 0 and 6 points. Each 1-minute video segment will have a score between 0 and 36 points.

The 3-AAT Observation ethogram, adapted with permission from Johns Hopkins University, was used to code both canine and human interaction during AAT sessions. The revised ethogram appraises the frequency of six domains of human interaction (affection, play, care, communication, comfort, withdrawal) and 24 subdomains of human behavior that can occur in an AAT session. The ethogram assesses the frequency, intensity, and duration of the interactions between the canine and child. Frequency is measured by a tally count and duration is assessed by rounding either up or down to the nearest 30 second mark. Each interaction has a code for intensity from 0 (not intense) to 3 (the most intense), and the mode of the interaction was entered to run the analysis.

The Strengths and Difficulties Questionnaire (SDQ) is a 25-item tool developed to assess five domains: Emotional Problems, Conduct Problems, Hyperactivity, Peer Problems, and Prosocial. The SDQ is the most used instrument in measuring therapeutic effect of interventions within the emotional state in children and adolescents ages 2 to 18 years, demonstrating reliable internal

consistency and validity. The SDQ has two versions, one to be administered at the initiation of therapy and then a follow-up version that includes two additional questions examining the impact of the therapeutic intervention. Scores from four behavioral domains range from zero ("normal") to 10 ("very high concerns"), while Prosocial domain scores are reversed so that 10 indicates "normal" behavior and zero signifies "very high concerns". The SDQ also assesses the total, impact, internalizing, and externalizing scores to provide a complete overview of the child's behavior during the past four weeks. Total scores are the sum of the behavior domains except the Prosocial domains and range from zero (normal) to 40 (very high). Impact scores range from zero (normal) to 10 (very high) and reflect overall distress and impairment interfering with daily social interactions. Internalizing scores reflect the Emotional Problems and Peer Problems domains, while Externalizing scores are the sum of the Conduct Problems and Hyperactivity domains. Both the Internalizing and Externalizing domain scores range from zero (normal) to 20 (very high). The initial SDQ was administered at the beginning of the study and the follow-up assessment was used subsequently every four weeks until the study concluded.

Lastly, the Positive and Negative Affect Schedule (PANAS) was administered weekly to measure therapeutic effects occurring in everyday life outside of the AAT session. The PANAS is a 20-item questionnaire utilizing a 5-point Likert scale to assess positive and negative affect occurring the week prior to administration. Each domain has 10 items with scores ranging from 10 to 50, with lower scores reflecting lower levels of positive or negative affect and higher scores signifying higher positive or negative affect. Total scores on each scale are obtained by adding the scores for each item. Analysis of the PANAS demonstrates very good internal consistency reliability, with alphas ranging from 0.86 to 0.90 for Positive affect and from 0.84 to 0.87 for Negative affect.

PRINCIPAL INVESTIGATOR
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PURPOSE OF STUDY
This purpose of this study is to evaluate the effect of services for children with developmental delay or autism spectrum disorder while using a dog trained or toy plush dog in therapeutic techniques. This study's aim is to see if therapy sessions with the dog or plush toy results in an improvement in your child's social and emotional abilities. Before you decide to allow your child to participate in this study, it is important that you understand why the study is being done and what will be involved. Please read the following information carefully. Please ask the principal investigator if there is anything that is not clear or if you need more information.

DESCRIPTION OF STUDY
Your child will be randomly assigned to one of two study groups; one includes animal-assisted therapy sessions with a live dog while the other group uses a toy plush dog. Activities involved in this study include animal-assisted therapy sessions lasting 30 to 60 minutes that focus on your child's identified developmental, social, emotional, and coping concerns. You will be provided with home therapeutic techniques to practice with your child in-between sessions. Therapeutic sessions will occur weekly. You will be asked to complete a set of assessments on your child's development, social-emotional skills, functioning, parent-child interactions, and intelligence quotient throughout the study. If able, your child will indicate their level of anxiety before and after each therapy session using a picture of a thermometer with varying levels of anxiety. You may be asked to report how you feel your child's socialization and emotional behaviors were since the last therapy session. Adolescents may also be asked to self-report how they feel their socialization and emotional behaviors were after the last therapy session.

Animal-assisted therapy sessions include techniques aimed to help your child with identified concerns in social and emotional behavior. The dog is trained to assist your child to engage in social interaction, like playing gently and taking turns during a game. Animal-assisted activities include playing fetch and other turn-taking games, assisting the dog to complete puzzles, coloring pictures with the dog, petting the dog, and grooming the dog. The dog can also give "hugs" if your child is anxious by leaning his body gently against your child's legs. Free play with the dog will be allowed once your child and dog have built a relationship. The sessions with the dog will last between 10 and 15 minutes, then the remaining time will be spent discussing home therapy techniques to practice until the next session. Research personnel who have been training the dog may be present to assist the dog during the session, and Dr. Kilmer, the dog's owner and handler, will be present while the dog is in the therapy session with your child.

Participants in the toy plush dog group will receive the same therapy content and will be encouraged to interact with the plush dog. They will have the option to brush the plush dog's "fur", hug him, talk with him, and pet him. The plush dog can be moved around in the room to accommodate different therapeutic activities during the sessions.

All therapy sessions in the clinic will be video recorded for research purposes.

RISKS
Minimal risks are associated with this studies. Other than the normal emotional risks associated with therapy of this type, the only risk involved with this research is normal minimal risk involved with interacting with a well-behaved dog The dog is being trained as a therapy and service dog and attends weekly sessions with experienced trainers. Dr. Kilmer is being educated to properly perform animal-assisted therapy sessions. The dog will be on leash throughout the session and will be removed if he or your child appear to be distressed. There is a very small risk of injury from the dog (e.g., scratching, teething/nipping); however, given the extensive training of the dog and continuous monitoring of the dog at all times, this risk is considered minimal and unlikely.

BENEFITS
There are no direct benefits to you for allowing your child's assessments to be used in this research; however, results from this research could improve therapeutic care of children with developmental delay or autism spectrum disorder. Your child will also receive a plush toy that looks like the dog and a trophy for participating in the study.

CONFIDENTIALITY
Participant data will be kept confidential to the extent allowed by law and University policy. Your responses to the questionnaires and evaluations will have all identifying information removed. The principal investigator will keep data in her computer that is password protected. Notes, interview transcriptions, and any other hard copies of identifying participant information will be secured in a locked file cabinet in the personal possession of the principal investigator. Videos of therapeutic sessions will be downloaded to principal investigator's password-protected university-issued computer within 24 hours and then immediately deleted from the camcorder device. Only research personnel will have access to these files, unless otherwise required by law. The principal investigator is legally obligated to report specific incidents which include, but may not be limited to, incidents of abuse and suicide risk.

Your child has been identified at-risk for developmental delay or autism spectrum disorder by his/her primary care provider (PCP), who then referred your child to the EMSON Access for Autism program for further developmental assessment. As such, the referring PCP will receive the results of the assessments as well as recommendations for identified concerns. Also, the investigators may request your consent to obtain medical records from the referring provider, allied health, and specialty clinics who take care of your child. Your child's schoolteacher and staff may be contacted to provide records or complete forms necessary for the evaluations if indicated. Aside from this, the co-investigators request permission to use assessment results in research on pediatric autism and developmental delay.

CONTACT INFORMATION
If you have questions at any time about this study, or you experience adverse effects

as the result of participating in this study, you may contact the co-investigators, whose contact information is provided on the first page. If you have questions regarding your rights as a study participant, or if problems arise which you do not feel you can discuss with the co-investigators, please contact the University of Arkansas Institutional Review Board at 1-479-575-2208.

VOLUNTARY PARTICIPATION
Both you and your child's participation in this study is voluntary. It is your decision whether or not to allow your child to take part in this study. If you decide to allow your child to take part in this study, you will be asked to sign this consent form. If your child is able, they will also be asked to provide their assent. After you sign this consent form, you and your child are still free to leave at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the co-investigators.

CONSENT
I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Parent/Guardian signature _____ Date _____

Child assent:
I have discussed this study with my parent/guardian, and I agree to participate. I understand that even if they agree, it's okay if I choose not to participate or change my mind about participating later.

Child signature _____ Date _____

Investigator signature _____ Date _____

University of Arkansas System

Document Overview

Description: Human animal interaction between children and a live canine or toy plush dog

Explanation:

Organization Doc Num:

Protocol Summary

Protocol Number: 2307483365

Sequence Number: 3

Status: Active - Open to Enrollment

Expiration Date: 10/10/2025

Last Approval Date: 10/11/2024

Investigator: Michele R Kilmer

Protocol Details

Type: Expedited

Summary/Keywords:

Application Date: 09/21/2024

Reference ID1:

Reference ID2:

FDA Application No:

Title: Human animal interaction between children with ASD and a live canine or plush toy dog

Areas of Research

Code	Description
000001	All Research Areas

Organizations

Type	Organization	Address
Performing Organization	University of Arkansas	University of Arkansas 1125 West Maple Street 316 ADMN Bldg, Fayetteville, AR 72701 USA

Funding Source

Type	Number/Code	Source	Title
Internally Funded/ Unfunded Research	unfunded	N/A	

Protocol Number:	2307483365		Expiration Date:	10/10/2025
Investigator:	Michele R Kilmer		Last Approval Date:	10/11/2024

Subjects

Subject	Count
Children	150

Investigators

Person Name:	Michele R Kilmer		Role:	Principal Investigator
Units:	CC012723	UAF | NURS | Department of Nursing	Affiliation:	Supervisor
Office Phone:	479-575-5466		Mobile:	
Email:	michelek@uark.edu			

Study Personnel

Person Name	Role	Affiliation	Email
Danielle Randolph	Study Personnel	Non-Faculty	dr063@uark.edu
Caroline Elizabeth Kilo	Study Personnel	Student Investigator	cekilo@uark.edu
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Claire Elizabeth Little	Study Personnel	Student Investigator	celittle@uark.edu
Terria Hawley	Study Personnel	Faculty	trhawley@uark.edu
Ava Wisinger	Study Personnel	Student Investigator	acwising@uark.edu

Training

Person Name	Description	Date Completed	Expiration Date
Danielle Randolph	CITI, Basic/Refresher Course - Human Subjects Research, Biomedical Research, Basic Course, 1	02/21/2025	02/21/2028

Other Roles

Person Name	Role	Affiliation	Email
Minju Hong	Data Integrity Manager	Faculty	minjuh@uark.edu

<h1 style="text-align:center">Questionnaire</h1>

Questionnaire Name: Human Subjects Protocol Interview

Description: Human Subjects Protocol Interview

Module: IRB   **Sub Module:**

Protocol Number: 2307483365   **Sequence Number:**   3

Principal Investigator: Michele R Kilmer

Title: Human animal interaction between children with ASD and a live canine or plush toy dog

- **What is the purpose of this research? Please explain both why you are doing the research (class assignment, thesis, etc.) AND/OR state your hypothesis. See attachment is not a sufficient response.**

  The proposed project will investigate the human-animal interaction (HAI) and bond (HAB) between a canine trained in therapy techniques or a canine plush toy and youth with autism spectrum disorder (ASD) or developmental delay (DD) during animal-assisted therapy (AAT) sessions. The purpose of this study is to explore identified gaps in knowledge pertaining to AAT in pediatric ASD and DD care management. Specifically, we seek to document human interaction between either a live canine or the plush toy canine during AAT sessions, evaluating prosocial behaviors observed during and after AAT sessions. This study will address the following research questions: 1. How do children with autism ages 2 to 18 years interact with a live canine during AAT sessions? 2. How do children with autism ages 2 to 18 years interact with a toy plush dog during AAT sessions? 3. Is there a difference in HAI in the live canine group and the toy plush dog group? 4. Is there a difference in prosocial behavior observed during AAT sessions between the live canine group and the toy plush dog group? 5. Is there a difference in behavior after AAT sessions between the live canine group and the toy plush dog group?

- **Are you collecting data about living individuals?**

  Yes

  - **Are you collecting data through intervention or interaction with these individuals?**

    Yes

    - **Beyond the basic Participant Types (children, UofA Students, adults, etc.) named elsewhere in this application, do you have a target population (particular group of people) you want to recruit? Some examples might be students in a particular class, members of a particular group or network, people in a specific age range (whether adult or minor), children in a particular school or class, etc.**

      Yes

      - **Describe your target population.**

        Dr. Kilmer collaborates with the local primary care providers who refer children, ages 18 months to 18 years, at risk for developmental delay or autism spectrum disorders to the Access for Autism (A4A) program for further developmental evaluation and care management. Children receiving care management by the A4A program who have developmental or behavioral concerns can volunteer to enter this study.

      - **How are you recruiting participants? Are you standing in a public place asking people to take a survey, sending out introductory emails, posting an ad or blurb on a website or social media, posting a flyer in a public location, etc.? **Please note that all recruitment materials will need to be uploaded in the Notes and Attachments section.**

Dr. Kilmer will discuss the study with parents/guardians whose children have been referred to the A4A program for further developmental evaluation. Participation in the study is voluntary and does not affect other services provided by the A4A program.

- **Provide a brief description of the procedures involving the participants.**

  Participants will be divided into 2 groups: one group will interact with the live canine while the other group will interact with a toy plush dog identical to the canine. Dr. Kilmer will use a variety of behavioral and developmental evaluations to identify concerns and provide strategies for home therapy to improve delays for both groups. The O'HAIRE Coding System and 3 AAT Observation ethogram will be used to observe and code human behavior during all sessions for both groups. Additionally, participants ages 8 years and older who are cognitively capable will be asked to self-report their emotional state before and after each AAT session using an 11-point Likert scale chart in the shape of a thermometer, with ranges from "no distress/totally relaxed" to "highest anxiety/stress that you've ever felt." A caregiver satisfaction and perspectives of AAT integration in therapy sessions will be assessed via surveys. Demographic data including participant age, gender, race/ethnicity, referral source, prior medical diagnoses, age of ASD or DD diagnosis, medications, and prior allied health or psychological therapies will be collected on all participants. Dr. Kilmer will incorporate AAT into the therapy sessions at the A4A clinic that are guided by the developmental, adaptive-functioning, and social/emotional assessments to target gross and fine motor skill, language, social, emotional, and adaptive-functioning development. Parents will be given handouts that are designed to address deficits identified by the assessments. The O'HAIRE Coding System will be used to observe and code human behavior during AAT sessions. Observable behaviors categories captured by the OHAIRE Coding System include Interactive Behaviors (Social Communication & Environmental Interaction), Emotional Display (Facial, Verbal), and Interfering Behaviors (Aggression, Overactivity, Isolation). The OHAIRE-V3 assessment will be used to calculate a human-animal bond score to quantify the interactions taking place between the pediatric participants and the animal. The ELAN Coding software will be used to achieve high inter-rater reliability through precise timing of observed interactions. The 3 AAT Observation ethogram assesses 26 canine behaviors during human-animal interactions. The ethogram is divided into three categories: affiliative indicators, moderate stress indicators, and high-stress indicators. All sessions will occur at the A4A clinic, which is located on campus in the Epley Center for Healthcare Professionals. The first interaction between the canine and the participant will focus on introducing the two and facilitating a bond through play, such as petting or brushing the canine, or throwing a ball. The canine will be present to interact with children as they are learning their skill for that week. For example, the canine will interact with the participant while the participant is learning a new skill, such as improvement in handwriting, and the participant will be able to interact and play with the canine if the participant focuses on completing the therapy assignment. Likewise, participants will earn points if they perform their therapy strategies at home and can use those points to interact and play with the canine at their next therapy session. Plush dog toys who look like the canine will be given to pediatric participants in both groups as incentive to perform their home therapies.

- **How long are the procedures likely to take? Include duration and frequency.**

  The A4A weekly therapy sessions will last about 30 to 60 minutes, with opportunities for participants to interact with the canine or toy plush dog intermittently throughout the session, depending on the therapy activity.

- **How will information be given to people to get their informed consent to participate in this research? Answers should include specific methods (e.g., verbal consent, information handout, online consent form, full consent form requiring signature documentation.) **Please note that consent materials -- from a script for verbal consent to full consent forms that require participant signature -- must be uploaded in the Notes and Attachments section.**

  Dr. Kilmer will contact parents/guardians of potential participants to explain the AAT program and gage their interest. If interested, parents will come to the A4A clinic on the first floor of ECHP to meet the canine and sign the informed consent form. Verbal assent will be obtained from pediatric patients who are cognitively able to give it.

- **Does data collection rely on a scheduled event, such as a convention or specific date?**
  No

- **How will your data be collected? Include all that apply: online, on paper/in person, audio and/ or video recordings. **Please note that all data collection materials will need to be uploaded in the Notes and Attachments section. This includes: surveys, questionnaires, interview questions or anything that is given to or asked of a participant.**
  Data will be collected in the initial consultation form for the A4A clinic, through performing developmental, behavioral, social/emotional, and adaptive-functioning assessments, and with surveys. The following will be used to collect data: 1. A4A Intake form: all participants 2. Developmental screenings such as Ages and Stages Questionnaire- 3rd edition: 1 month to 5.5 years; Ages and Stages Questionnaire: Social/Emotional- 2nd edition: birth to age 6 years; Social and Emotional Assessment/ Measure: 2 to 66 months; Strengths and Difficulties Questionnaire: 3 to 16 years; Positive and Negative Affect Schedule: 9 to 14 years; Vineland- 3rd edition: 3 to 21 years; Social Responsiveness Scale- 2nd edition: 2.5 to 18 years; Standford-Binet IQ Test: 2 to 18 years; Autism Diagnostic Observation Scale-2: 18 months to adulthood; and Childhood Autism Rating Scale- 2: 2 years to adulthood. All AAT sessions will be recorded after receiving consent from families to retroactively code participant behavior during sessions with the OHAIRE and 3 AAT ethograms.

- **How will your data be stored? Include all that apply: electronically, on paper, audio and/or video recordings.**
  Survey data will be stored in an Excel spreadsheet and Qualtrics, which is a HIPAA-secured software with which caregivers of youth with complete on a personal device (iPad, laptop, cellphone).

- **How will that data be kept secure?**
  Data saved in the Excel spreadsheet will only be accessible by approved research staff and stored in Dr. Kilmer's password protected laptop. Any hard-copy measures of documents will be stored in Drs. Kilmer's locked office in a locked filing cabinet. Video files will be downloaded from camcorders directly to Dr. Kilmer's secured laptop. Only authorized research personnel will have access to these files and only participant numbered IDs will be included on assessment documents. Participant identifying information and associated ID numbers will be stored in Dr. Kilmer's lab in a password protected computer on a password protected document. Dr. Kilmer and approved research personnel will have access to participant ID information but will mainly utilize participant ID numbers. All video files will be downloaded to Dr. Kilmer's computer within 24 hours and then immediately deleted from the camcorder device. Video files will be stored on a password-protected computer as password-protected documents.

- **Minimal Risk is defined as risks of harm not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Will participants be exposed to more than minimal risk? Include in your consideration the potential of mental risks if asking sensitive questions, or legal or reputational risks in case of breach of confidentiality.**
  Yes

  - **Describe the risks in question and any precautions that will be taken to minimize those risks.**
    Participants will not be exposed to more than minimal risks while receiving developmental or behavioral evaluations. Participants will be exposed to the canine during therapy sessions. The canine will be removed if signs of fatigue, fright, or irritation appear. He is trained off leash and will be wearing a harness which can easily be tethered to his crate as needed. Dr. Kilmer will assess the disposition of the pediatric participants before allowing the canine to come to the room and will not allow the canine to participant if the pediatric participant's behavior is disruptive or potentially

dangerous for the canine. Dr. Kilmer is the canine's trained handler and is educated in observing his behavior and will place him in the crate if he appears fatigued or irritated, or if the participant no longer wants to play or pet him.

- **Are there any direct benefits to the participants for participating in this study?**
  Yes

  - **Describe the benefits participants will or may receive.**
    Pediatric participants will receive one plush toy that looks like the canine or toy plush dog they are working with.

- **Will the proposed research involve deception or the withholding of information from participants?**
  No

- **Will the proposed research necessitate medical clearance from a physician prior to participation?**
  No

- **Will the proposed research involve gathering biological samples (blood, tissue, etc.)?**
  No

- **Will the proposed research involve administering of substances or providing food and drink, other than water, to participants?**
  No

- **Will the proposed research involve physical exercise or conditioning?**
  No

- **Does the research require review by a non-UofA IRB?**
  No

- **Does this research require approval from another institution or agency, such as a school or privately owned business?**
  No

Protocol Number: 2307483365
Investigator: Michele R Kilmer

Expiration Date:
Last Approval Date: 10/11/2024

New/Changed Attachments

Description	Last Updated	Updated By
PANAS assessment	07/30/2023 19:06:26	michelek@uark.edu
A4A Intake Form	07/30/2023 19:08:55	michelek@uark.edu
Demographic data	07/30/2023 19:11:26	michelek@uark.edu
3 AAT Observation Ethogram	07/30/2023 19:26:49	michelek@uark.edu
Informed consent	09/19/2023 14:06:54	iwindwal@uark.edu

Protocol Notes

Comment	By	Time
Dr. Kilmer and the canine completed therapy dog training in June 2022 and will be evaluated as a handler/canine therapy team in December 2023. The canine is still in training learning ASD specific service dog tasks. This training is scheduled to be completed in December 2023 and will be evaluated as a service dog at that time.	michelek@uark.edu	09/05/2023 18:08:14
Nursing undergraduate Honors students have been educated in training techniques used for the canine, Gryffin, who will be participating in this study. Students meet with the canine individually and as teams, training him in voice recognition and to obey commands that will be used during the AAT sessions. Example of the commands are sit, stay, come, wait, drop it, bring it, off, down, say Hi, hug, roll the ball, and fetch. They have also worked with the canine on and off leash and have taught him how to greet others properly without jumping, how to hug, how to say hi, and how to ask to be petted. The canine is accustomed to them and knows their voice. He obeys their commands well.	michelek@uark.edu	07/30/2023 19:35:41
The Stanford-Binet Intelligence Quota Test gauges intelligence through five factors of cognitive ability: fluid reasoning, The Standford-Binet is published by the WPS Publishing company and is subject to copyright laws, therefore, it cannot be uploaded. knowledge, quantitative reasoning, visual-spatial processing and working memory.	michelek@uark.edu	07/30/2023 19:35:41
The SRS-2 identifies social impairment associated with ASD and quantifies its severity. It can be used for children with developmental delay as well. Domains include social awareness, social cognition,	michelek@uark.edu	07/30/2023 19:35:41

| Protocol Number: | 2307483365 | | **Expiration Date:** | |
| **Investigator:** | Michele R Kilmer | | **Last Approval Date:** | 10/11/2024 |

Protocol Notes

Comment	By	Time
social communication, social motivation, and restricted interests and repetitive behavior. The Social Responsiveness Scale is published by the WPS Publishing company and is subject to copyright laws, therefore, it cannot be uploaded.		
The Vineland-3 measures 5 domains of adaptive functioning: communication, daily living skills, socialization, motor skills, and maladaptive behaviors. The Vineland-3 is published by the WPS Publishing company and is subject to copyright laws, therefore, it cannot be uploaded.	michelek@uark.edu	07/30/2023 19:35:41
The ASQ:SE-2 evaluates seven areas of social-emotional functioning in children ages 1 - 72 months: self-regulation, compliance, social-communication, adaptive functioning, autonomy, affect, and interaction with people. The ASQ: SE-2 is published by the Brooks Publishing company and is subject to copyright laws, therefore, it cannot be uploaded.	michelek@uark.edu	07/30/2023 19:35:41
The Ages and Stages Questionnaire, 3rd edition, used for children ages 1 - 66 months and assesses gross motor, fine motor, communication, problem-solving, and personal-social development. The ASQ-3 is published by the Brooks Publishing company and is subject to copyright laws, therefore, it cannot be uploaded.	michelek@uark.edu	07/30/2023 19:35:41
The Strengths and Difficulties Questionnaire (SDQ) is a brief behavioral screening questionnaire about 3-16 year-olds. It exists in several versions for differing ages to meet the needs of researchers, clinicians and educationalists. The initial Strengths and Difficulties Questionnaire(SDQ) will be used on participants ages 3 - 17 years to assess psychological attributes in the following categories: emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and prosocial behaviors. The Strengths and Difficulties Questionnaire published by Youth in Mind and is subject to copyright laws, therefore, it cannot be uploaded.	michelek@uark.edu	07/30/2023 19:35:41
The O'HAIRE canine behavior ethogram will be used to assess human-animal interaction. The manual is too large to upload and is available upon request.	michelek@uark.edu	07/30/2023 19:35:41
The Autism Diagnostic Observation Schedule-Second Edition (ADOS-2) is a standardized assessment tool that helps providers diagnose autism spectrum disorders (ASD) in children and adults. The ADOS involves a semi-structured play or interview session determined by the age and communication level of the individual. The ADOS provides standardized activities and questions that give the examiner opportunities to observe behaviors that are directly relevant to the diagnosis of ASD. The ADOS-2 incorporates the use of planned social activities designed for different developmental levels and	michelek@uark.edu	07/30/2023 19:35:41

Protocol Number:	2307483365	**Expiration Date:**	
Investigator:	Michele R Kilmer	**Last Approval Date:**	10/11/2024

Protocol Notes

Comment	By	Time
chronological ages that provide situations in which social interactions, communication and particular types of behaviors are likely to appear. The examiner chooses from five different modules depending on age (12 months through adulthood), language and developmental level. The assessment usually takes 40 - 60 minutes to complete. The examiner scores the ADOS-2 based on observations noted during the session on several aspects of social behavior. The score on the ADOS-2 indicates whether or not the individual's presentation is consistent with a diagnosis of an ASD. The ADOS-2 is published by the WPS Publishing company and is subject to copyright laws, therefore, it cannot be uploaded.		
The Childhood Autism Rating Scale-Second Edition (CARS2) is a 15-item rating scale used to identify children with autism and distinguishing them from those with developmental disabilities. It is empirically validated and provides concise, objective, and quantifiable ratings based on direct behavioral observation. It was normed on a sample of 1,034 individuals with autism spectrum disorders. This second edition of CARS expands the test's clinical value, making it more responsive to individuals on the "high functioning" end of autism spectrum disorders. The clinician rates the individual on each item, using a 4-point rating scale. Ratings are based on frequency of the behavior in question, its intensity, peculiarity, and duration. The CAR2 is published by the WPS Publishing company and is subject to copyright laws, therefore, it cannot be uploaded.	michelek@uark.edu	07/30/2023 19:35:41

Actions

Description	Comments	Action Date
Expedited Approval	Renewal-001: Approved	10/11/2024
Expedited Approval	Renewal-001:	10/11/2024
Assigned to Agenda	Renewal-001:	10/11/2024
Submitted to IRB	Renewal-001: Submitted to IRB	09/21/2024
Renewal Created	Renewal-001: Created	09/21/2024
Renewal Reminder Generated	Renewal Reminder Letter #2	08/20/2024
Renewal Reminder Generated	Renewal Reminder Letter #1	07/05/2024
Expedited Approval	Amendment-001: Approved	04/26/2024
Expedited Approval	Amendment-001:	04/26/2024

Protocol Number: 2307483365   **Expiration Date:**

Investigator: Michele R Kilmer   **Last Approval Date:**   10/11/2024

Actions

Description	Comments	Action Date
Assigned to Agenda	Amendment-001:	04/26/2024
Submitted to IRB	Amendment-001: Submitted to IRB	04/14/2024
Amendment Created	Amendment-001: Created	04/14/2024
Expedited Approval		09/19/2023
Assigned to Agenda		09/19/2023
Administrative Correction	Changing consent document format to PDF for approval watermark.	09/19/2023
Submitted to IRB	Submitted to IRB	09/05/2023
Specific Minor Revisions Required		09/05/2023
Delete Review	Online reviewer Ann M Killenbeck has been deleted. Deletion reason - Reviewer has not responded in a reasonable length of time; review is being reassigned to another board member.	08/25/2023
Submitted to IRB	Submitted to IRB	07/30/2023
Protocol Created	Protocol created	07/29/2023

Review Comments

Protocol Number:	2307483365	**Sequence Number:**	3
Principal Investigator:	Michele R Kilmer		
Title:	Human animal interaction between children with ASD and a live canine or plush toy dog		
Committee Id:	200	**Committee Name:**	IRB Expedited Review
Schedule Id:	45832	**Schedule Date:**	11/16/2024

Review Comments:

Positive and Negative Affect Schedule (PANAS-SF)

Indicate the extent you have felt this way over the past week.		Very slightly or not at all	A little	Moderately	Quite a bit	Extremely
PANAS 1	Interested	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 2	Distressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 3	Excited	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 4	Upset	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 5	Strong	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 6	Guilty	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 7	Scared	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 8	Hostile	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 9	Enthusiastic	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 10	Proud	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 11	Irritable	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 12	Alert	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 13	Ashamed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 14	Inspired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 15	Nervous	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 16	Determined	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 17	Attentive	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 18	Jittery	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 19	Active	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PANAS 20	Afraid	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Scoring:

> ***Positive Affect Score:*** Add the scores on items 1, 3, 5, 9, 10, 12, 14, 16, 17, and 19. Scores can range from 10 – 50, with higher scores representing higher levels of positive affect.
> Mean Scores: 33.3 (SD±*7.2)*

> ***Negative Affect Score:*** Add the scores on items 2, 4, 6, 7, 8, 11, 13, 15, 18, and 20. Scores can range from 10 – 50, with lower scores representing lower levels of negative affect.
> Mean Score: 17.4 (SD ± 6.2)

Your scores on the PANAS: Positive: ____   Negative: ____

Watson, D., Clark, L. A., & Tellegen, A. (1988). Development and validation of brief measures of positive and negative affect: the PANAS scales. *Journal of personality and social psychology, 54*(6), 1063.