Study Protocol and SAP: The development and evaluation of a novel Cat Assisted Training (CAT) intervention for youth with developmental disabilities and their family cat.

NCT05950672

October 24, 2024

Study Protocol and Statistical Plan NCT05950672

The development and evaluation of a novel Cat Assisted Training (CAT) intervention for youth with developmental disabilities and their family cat.

Initial IRB (HE-2022-29) Approval: March 13, 2023

Last IRB (HE-2022-29) Approval: October 24, 2024

Specific Aims:

The goal of this proposal is to develop and evaluate a novel Cat Assisted Training (CAT) intervention creating a unique active partnership between early adolescents with developmental disabilities (DD) and their family cat to promote physical activity, social wellbeing, and lasting feelings of responsibility.

Children with DD are 4 times more likely to be physically inactive compared to peers without disabilities, and with age their physical activity further declines [1], [2]. While various interventions have been successful at improving short-term physical activity, long-term compliance and generalizing behavior outside of the treatment setting can be a challenge. Barriers to long-term compliance include high cost, limited access to ongoing interventions and aging out of available programs. Early adolescence is especially challenging for children with DD, who often experience difficulties with social skills and in developing a sense of independence and responsibility. Comparatively greater supervision from parents/caregivers, while sometimes necessary, has the potential to impede practicing and obtaining these skills. Although extensive research has focused on identifying differences in physical activity and social skills of children with DD, there remains a critical need to develop innovative interventions that increase independent physical activity and social wellbeing.

There is increasing evidence that human-animal interactions (HAI) and Animal Assisted Interventions (AAI) can promote health benefits in children. Frequency and quality of HAI, including walking together, training and caretaking behavior, predict the strength of HAI relationships and benefits [3]. Companion animals have also been found to alleviate social anxiety and stimulate conversation in social situations [4], and can help improve the social- support network, integration, and the overall quality of relationships children experience [5]. In our own research, we have found that dog walking and dog training interventions have clear benefits for youth (ages 10-17) with DD and their dogs [6]. Importantly, in a separate line of research, we have found that cats possess many of the same qualities that make dogs successful as active AAI partners [7]. This CAT program was designed with a strong theoretical rationale, uniquely integrating joint activities and positive interactions known to promote feelings of attachment and social closeness in both humans and cats.

Domestic cats are one of the world's most popular companion animals. In the U.S. alone there are over 94 million cats compared to 90 million dogs [8]. Despite the prevalence of companion cats, relatively little research has examined human-cat interactions or activity-based-AAIs with cat partners [9]. There has been even less research on cat-child interactions, or the impacts of AAI participation on cat behavior or welfare. Therefore, there is a critical need to conduct more research on the cat-human bond and on cats as AAI partners. Myths about domestic cats (including false beliefs that cats are asocial or untrainable) have likely contributed to their underrepresentation in this field [8,9]. However

our research, and that of others, has empirically demonstrated that cats have the capacity to share strong secure bonds with their owners [7], can be trained (at any age) [10] and that lifetime experiences influence the quality of social interaction and relationship shared between cats and humans [11]. Although cats have appeared in the AAI literature as highly effective passive therapeutic partners (e.g. holding still for petting) including for children diagnosed with autism [12], there are compelling reasons why cats should be strongly considered as partners in more active AAIs, including cat-walking and training. Cats are smaller and weigh less than most dogs making them easier for participants (especially those with physical disabilities) to walk on leash, pick-up, and transport safely without assistance. Cat walking and training, while increasing in popularity [9], [13], is still viewed as novel and exciting- factors that encourage long term enthusiasm and engagement. Cats, like dogs, have needs for enrichment, exercise and bonding which can be addressed through high quality interactions with human caretakers. Finally, there are many people who have chosen to live with cats (over 45 million households in the US alone [14]), some of whom may not feel comfortable walking or training dogs. This should not preclude them from AAIs aimed at promoting physical activity. It is our responsibility to consider the possibility that *our current lack of data* about the domestic cat's full potential as an AAI partner could be unintentionally contributing to AAI recruitment and participation inequities [15]. More research is needed to promote evidence-based practices and accessibility.

We propose to address a *critical need* for more research in these areas through the following specific aims:

Specific Aim 1

To evaluate the nature and quality of bonds shared between cats and children with DD.

Specific Aim 2

To develop and evaluate the efficacy of a novel Cat Assisted Training (CAT) intervention aimed at increasing physical activity in early adolescents with DD.

Specific Aim 3

To evaluate the impact of a CAT intervention on social wellbeing and the child-cat bond.

Research Strategy

Significance:

This project will provide a multidisciplinary One Health approach to an AAI for early adolescents (8-17 years old) with a DD and their family cat. Limited research has focused on AAIs targeted at early adolescence [4]. We are not aware of any animal training interventions where the AAI partner is a cat. There is a critical need to develop intervention strategies that will promote the development of healthy physical activity behaviors, social skills and aid in developing a sense of independence and responsibility among adolescents with DD. AAIs have been credited with a wide range of positive health outcomes [4], [5], [16], [17]. Interventions involving an active partnership between a child and a family pet present an important opportunity to make AAIs more sustainable, by allowing learned intervention activities such as animal training, care, and walking together to continue in the home environment after the on-site intervention [16]. The relative novelty of cat training is expected to increase retention and

provide the long-term motivation to do so. Child-pet partnerships also capitalize on both the benefits of AAI and of pet ownership. While it has been found that child-cat bonds can benefit children, including those diagnosed with autism [12], and that stronger human-cat attachments lead to greater health benefits [18], many intervention strategies known to improve human-animal bonds and AAI health outcomes (including training and activity/walking interventions) have not been evaluated with cats.

This proposal considers the health and welfare of the child and cat, as well as the quality of the shared relationship. Our CAT intervention will emphasize an active partnership between the child participant and family cat, allowing both to develop important life-long skills over the course of six-week intervention. Child participants will learn fear-free handling and training techniques, how to walk a cat on harness and leash and will be given homework to help build responsibility with respect to cat care. Our prior data suggests that these activities should result in increased physical activity and improved social wellbeing in youth with DD - a group at high risk for physical inactivity and fewer opportunities for responsibility than peers without DD [19]. CAT is also expected to increase cat sociability [11], decrease cat stress in the presence of the child [7], and promote joint activity and stronger child-cat bonds. Increased physical activity is linked to better health in cats [20].

Innovation

Although cats outnumber dogs in the U.S., the efficacy of cat AAIs aimed at increasing physical activity, responsibility, and social wellbeing in early adolescents has not been evaluated. Dogs and horses are often employed in AAIs [4], [17], however not all individuals have equal access to these animals. The absence of activity based cat AAIs may represent a missed opportunity to reach a significant portion of the population [15]. This research is innovative because it focuses on the development and evaluation of a novel physical-activity-based Cat Assisted Training (CAT) intervention for early adolescents (8-17) with DD.

Justification and Feasibility

Cats are a common and accessible companion animal. There is ample scientific evidence that cats can be trained using positive reinforcement [7], [10]. Interest in cat walking has steadily increased, with 24% of owners buying cat leashes in 2017, compared with 17% in 2006 [13]. This year a new world record was set for the number of tricks performed by a cat in one minute (26 tricks). The cat was 8 years old; the cat owner began training her cat on her own when she was 11 years old [21]. Our team includes three experienced cat trainers (Drs. Udell, Vitale & Darling), who have successfully taught cat owners the skills included in the CAT intervention (Table 1) including how to walk cats on leash. Drs. Udell & Vitale have run 6-week long cat training camps at Oregon State University (OSU) for over four years (with 50 cat participants in a 2-year period) and cat training camps for youth. We have published on cat social behavior and human-cat bonds. Drs. Udell, MacDonald and Jiang have successfully developed and evaluated dog training and walking AAIs for youth with DD (age 10-17). Dr. MacDonald's specialty is physical activity and social behavior in youth with disabilities. Dr. Jiang is a statistician experienced with AAI research. Our team has the experience, facilities, interdisciplinary breadth, and collaborative track-record to successfully recruit participants, conduct the proposed CAT AAI and evaluate the outcomes. Given the rapid growth of scientific knowledge in the areas of AAI, HAI, and cat behavior in recent years, the development and empirical evaluation of new AAI programs targeted to meet the needs of early adolescents from diverse populations is especially critical. The methods of this

program are based on a strong foundation of theoretical knowledge related to the social benefits of joint synchronous activity (cat walking)[22], behavior analysis (benefits of incremental positive reinforcement-based shaping and training)[23] and attachment theory (cat-human bonding)[7], and our teams prior research on cat training and activity based AAIs with dogs.

Preliminary Data:

Cat training classes are likely to promote engagement and retention (Fig. 1): Preliminary data support the conclusion that there is strong community interest in participating in cat training classes. For example, Drs. Udell & Vitale offered five formal (6-week long) cat training classes to the public at Oregon State University over a two-year period. 100 kitten-owner pairs enrolled in the program during this time, with 50 assigned to the training class (experimental group); 86% of owners completed the 6-week program. Owners that completed the course attended 91% of the class sessions and 84% of them participated in research testing at baseline and follow-up. Cats also readily learned behaviors through use of positive reinforcement training. Successfully learned behaviors included "go to mat and stay", "sit", "stand", "target", "walk on harness with leash" and more advanced behaviors such as "stay" while in a kayak. Drs. Udell & Vitale have also offered multiple highly successful summer cat training camps where local youth were taught to train shelter/foster cats.

Figure 1: *Cats engaging in activities integrated into CAT; walking on leash, positive reinforcement training, and sociability tests conducted as part of prior research studies and outreach initiatives by our research team.*

Cats share many traits that have predicted AAI success in other species: Prior research suggests that the quality of attachment between human and animal AAI participants is an important predictor of health outcomes and AAI success [6], [18]. Members of our research team have evaluated cat-owner attachment bonds by exploring if cats can be categorized into the same secure and insecure attachment styles in a strange situation as seen in humans [24] and domestic dogs [25]. Drs. Vitale and Udell have found that like human infants and pet dogs, kittens (n = 70) and adult cats (n = 38) can display either secure or insecure attachment styles toward their adult owner, with the majority (64 - 69%) displaying a secure attachment (similar to the dog and human literature). What we have found in our work looking at dog-child attachment, is that often stable caregiver attachment relationships have not yet been established between children and their dogs prior to intervention, and that intervention participation significantly increases secure attachment formation between children and their animal partners [25]. We plan to evaluate this in cats.

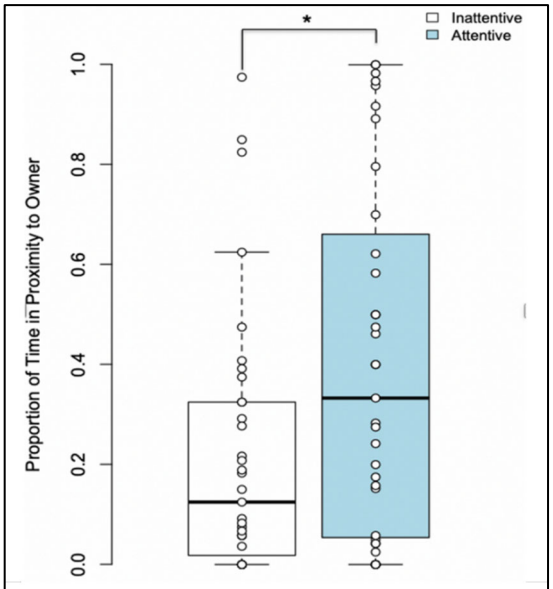

Figure 2: *Cats were significantly more sensitive to their owner's attentional cues following training classes and spend significantly more time with their owner when they were attentive vs inattentive ($p < .05$).*

Research by Drs. Vitale and Udell has also indicated that while individual cat behavior can vary, most pet cats actively seek out social interactions with human caretakers and are highly sensitive to human social cues. For example, adult pet cats participating in a sociability test spent on average 60 - 70% of a 2-min session seeking the proximity of an attentive owner [11]. In another study, 50% of cats chose to engage in social interaction with a human, over access to a preferred food item, toy and scent object ($p < .01$) [26], 37% choose their favorite food over social interaction (for many of these cats social interaction was their second choice). Interest in owners and interest in food are both useful starting points for training.

Human-cat interactions, including participation in training classes, can also have a positive impact on cat behavior and cognition. For example, we found that after participation in six-weeks of cat training classes with their owner, cats were significantly more responsive to their owner's attentional cues and spent significantly more time in proximity to their owner when the owner was attentive to the cat (Fig. 2). Cats in the control group (no training experience) did not display this level of sensitivity to their owner's attentional state.

The proposed study will address gaps in the current literature by providing more information about cat-child attachment bonds, the efficacy of a novel active CAT intervention and evaluation of the potential behavioral and social health and wellbeing outcomes of AAI participation for both human and cat participants.

Our team has experience developing and evaluating successful training & physical activity AAIs:

Drs. Udell, MacDonald and Jiang have previously developed, evaluated and published data on successful dog walking and training-based AAIs aimed at promoting physical activity and social wellbeing in children with DD. Drs. Vitale and Darling have both participated in the implementation of those interventions and are therefore familiar with the intervention approach. This prior dog AAI work was conducted with the support of the NIH [R21HD091895], and successful recruitment of children and adolescents with DD (N=30). We successfully met all study aims, resulting in published outcomes and measurable impact (e.g., presentations, media features, and growth to an R01 award [R01HD101098] that has allowed for regional expansion of our program to sites across the Pacific Northwest). The current proposal benefits from our experiential knowledge of what is feasible and achievable within the proposed timeline given our unique population, methods, and aims.

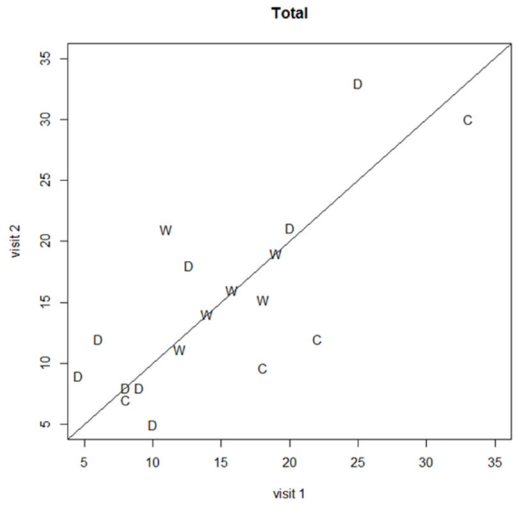

Figure 3: *Adolescents report more frequent dog walking, training and playing after a Dog Training AAI (D), compared with dog-walking alone (W) and no training controls (C). Symbols above the line indicate higher levels of these activities after intervention. (visit 2)*

In our prior work, we found that adolescents reported greater feelings of responsibility towards their dog, including increased rates of walking and training after participation in a dog training-based AAI (Fig. 3). The relationship between dogs and children improved, with significantly more secure

attachments between dogs and children after the AAI [6]. Given strong parallels in the theoretical framework and given the current state of scientific knowledge about cat-human relationships and cat social behavior, we predict similar outcomes for our cat-based intervention.

Experimental Approach:

Participants

50 early adolescents with a DD, between the ages of 8-17 years whose family includes at least one cat at the time of enrollment (see Sample Size Justification & Data Analysis) will be recruited from Corvallis OR and the surrounding communities through schools, community-based programs serving children with developmental disabilities (DDs) and through social media). A DD will be confirmed through parent report (e.g., initial recruitment conversations, and documented through demographic questionnaire). Although developmentally appropriate and adapted pedagogical techniques will be implemented within all intervention protocols, inclusion criteria for child and cat safety require all participants to follow basic instructions. To assess this, participants will complete the Head-Toes-Knees-Shoulders task (HTKS) [27]. This task requires participants to follow basic and more complicated instructions, including rule changes. To participate a minimum score of 1 (range 0-2) on 90% of the test items will be required of participants. For safety cats showing signs of aggression towards humans will not be eligible to participate. Cats will be carefully monitored to ensure their welfare during all activities. Because restricting the age of cats could limit human participant eligibility, and because there is evidence that a cat's age is not a reliable predictor of training success [10], for the proposed study we will allow any cat over 8 weeks to participate as long as they meet the above criteria, and will collect data on age as a variable. In recent years, we have successfully taken this approach with our dog training AAIs. Dyads meeting eligibility requirements will be randomly assigned (Randomized Control Trial) to either the CAT intervention (n=25) or Control (n=25) group after completing the consent/assent process. Dyads assigned to the control group will have the opportunity to participate in training classes after study participation is complete to ensure equal access to a potentially beneficial AAI. Each class will last 45-min for 6 sessions (see Table 1).

Study Groups: There will be 3 assessments per participating dyad over the course of 1 year; after initial enrollment (baseline), after six weeks (post-intervention or time matched control) and 1-year after enrollment. All participants (experimental & control groups) will complete each of these assessments.

CAT intervention Group

The experimental group will take part in the CAT intervention (Table 1) after baseline assessments. All cat-training methods will be positive reinforcement based, using owner-approved food, toys and social reinforcers (e.g. petting). Children will learn about cat body language, behavior and proper cat handling techniques.

Control Group

Control participants will complete the same three assessments as the CAT intervention groups but will not participate in the CAT intervention. After the completion of the third assessment (end of proposal-related data collection), control participants will be offered the opportunity to participate

in the cat training classes. This will ensure equal access to any benefits that might occur as an outcome of the intervention.

Cat Assisted Training Intervention

We predict that participation in the CAT intervention, which will teach children with DD how to use basic behavioral principles and positive reinforcement skills with their cats will facilitate increased opportunity and motivation to engage in joint physical activity (walking, training), responsibility-taking and will improve social wellbeing including quality of interactions between child and cat. The CAT intervention will be a six-session cat training and socialization camp, with each session lasting approximately 45 minutes. Over the course of the 6 session camp children will learn about cat body language and proper cat handling. They may also train their cat to walk in harness/leash, sit on command, and train trick behaviors as a final project. Trained assistants (one assistant per child) will help children train their cat using positive reinforcement training techniques. Breaks will be taken as needed or at least for 5 minutes, every 15 minutes. Focus will be on providing children with a better understanding of cat body language and how to train basic behaviors in order to facilitate enjoyable independent cat-human interactions at home. All training methods used with cats in the CAT intervention will be positive reinforcement based, using owner-approved food treats, toys or social engagement as reinforcers and/or lures where appropriate. An outline of activities and homework for the 6 session CAT intervention can be found below:

Table 1. *Outline of activities and homework for the 6-session CAT intervention*

Training Session	In-Class Content	Homework
Session 1:	Cat body language, Fitting harness & leash	Harness & leash training (positive associations)
Session 2:	Target training to facilitate walking; Come	Targeting with and without cat's harness/leash
Session 3:	Practice walking in harness/leash; Watch me	Work on watch me, come & practice walking
Session 4:	Practice walking in harness/leash; Sit	Work on training sit; practice walking
Session 5:	Practice walking in harness/leash; Go to mat	Work on go to mat; practice walking
Session 6:	Training challenge: Walk a course, stop and perform learned behaviors along path	Work on behaviors; practice walking; schedule 6-week assessment

Approach and Assessments:

Specific survey and behavioral assessments for each specific aim are outlined below. During assessments children and a parent/adult household member will complete several short, validated questionnaires. There are adaptable procedures, allowing for flexibility in administration. Participants can fill out the questionnaire on their own or an assessor can read aloud and allow the participant to respond. Scoring will conform to standard methods specified for each assessment. Cat-specific questionnaires have been adapted from previously validated animal questionnaires. All child and cat assessments will occur at each of the three assessment time points (Baseline, six weeks and 1 year). In total, assessments will include 4 pages of survey questions to be completed by the child, one 11-page

survey about the cat's behavior to be completed by a parent/adult in the household, and 8 minutes of behavioral testing by the cat and child during each assessment. Cat's will also participate in one additional behavioral attachment test with the primary adult caretaker during the initial assessment for initial paired comparison with child-cat bonds.

Aim 1*:* To evaluate the nature and quality of bonds shared between cats and children with DD.

Our hypothesis is that cats and children will show evidence of bonds prior to intervention. However, the quality and type of relationships shared between cats and children are predicted to be variable and less secure than cat-adult bonds initially. *Note: *The successful completion of Aims 2 & 3 is not dependent on the presence of secure attachment bonds between children and cats prior to AAI participation.* We expect CAT participation to improve attachment scores by week 6 (Aim 3), similar to what we have observed in our dog AAI research [6].

Aim 1 Assessments:

1. Behavioral Attachment Test: A cat sociability [11] and Secure Base attachment test [25] will be conducted to evaluate the cat-child bond (and the cat-adult bond at baseline). The cat's contact, proximity seeking, gaze, exploration, play and avoidance behavior will be evaluated over a series of 2-minute sessions (8 minutes total) where the child (or parent) is either present and passive, present and attentive, absent or reuniting with the cat. Behaviors will be double coded from video (to assess inter-rater reliability), coders will be blind to group assignment. Attachment style classifications will be made in line with previously validated methods [7].

2. Child-Cat Relationship Surveys: Children will complete a 1-page Children's Treatment of Animals Questionnaire (CTAQ) [28], 1-page Pet Care Responsibility Inventory [29], and a 1-page Lexington Attachment to Pets Scale (LAPS) [30]. These will characterize initial child-cat attachment (Aim 1) and to evaluate AAI outcomes related to predicted strengthening of the child-cat bond at 6-week and 1-year assessments (Aim 3).

Aim 2: To develop & evaluate the efficacy of a novel Cat Assisted Training (CAT) intervention aimed at increasing physical activity in early adolescents with developmental disabilities.

Our hypothesis is that participation in this novel CAT intervention will result in high participant retention and significant improvement in study related physical activity goals when compared with baseline measures, and when compared with a randomized control group.

Aim 2 Assessments:

1. Evaluation of CAT intervention retention: Our retention goal for this program is 68% (overall) - 76% (experimental group), as this is what we achieved in our prior dog walking/training AAI [NIH R21HD091895]. Lower retention would not rule out future CAT interventions but would signal that improvements may be needed to increase effectiveness. If attrition occurs, we will evaluate retention

across the course of the six-week CAT intervention using a survival curve to help identify any elements that could have contributed.

2. Evaluation of CAT intervention for increasing joint physical activity: As in our prior research evaluating dog training AAIs, survey items about pet walking, training and joint activity found on the validated Pet Care Responsibility Inventory [29] will be used to determine if intervention participation predicts a subsequent increase in joint physical activity (including walking and training behaviors) in CAT participants after the intervention, when compared with baseline measures and the control group. At each training session participants will also be asked if they completed their training and walking homework in the prior week, providing information about engagement that can be used to guide future development of the CAT program. This information will guide the development of our final program for our R01 proposal, where we will conduct a larger scale study of the CAT program, collecting additional physical activity data using accelerometers.

3. Evaluation of cat training success: We will evaluate the training success of cats across the behaviors presented in Table 1, primarily to help inform (and modify, if needed) future training strategies and goals. We have found in past studies that the number of behaviors an animal learns during the intervention itself is less important to AAI health-related outcomes than the process of engaging in the intervention [6], nonetheless we aim to make the AAI training goals and methods as successful and data driven as possible. We will also evaluate behavior changes across assessment time points using the validated 11 page Feline Behavioral Assessment & Research Questionnaire (Fe-BARQ) [31] completed by a parent/adult in the household.

Aim 3: To evaluate the impact of a CAT intervention on social wellbeing & the child-cat bond.

Our hypothesis is that participation in a novel CAT intervention will result in increased feelings of social wellbeing, increased attachment towards the family cat and will promote greater independent responsibility for the family cat by adolescent participants with DD when compared to baseline measures, and controls. We also predict that we will find behavioral evidence of increased sociability and higher rates of secure attachment among cat-child dyads following intervention when compared to baseline.

Aim 3 Assessments:

1. Attachment Measures: The attachment test [25] and the Child-Cat Relationship Survey outlined under Aim 1 Assessments will be used to compare the quality and strength of the child-cat bond before and after CAT intervention participation and to compare child-cat bonds between intervention participants and controls at 6 weeks and 1 year. Importantly these measures provide information on attachment from the perspective of both the human (survey) and the cat (behavioral assessment).

2. Social Wellbeing Measures: Human participants will complete a 1-page Emotional Support survey validated for children ages 8-17 [32], and cats will complete the sociability test described in Aim 1 before and after intervention participation. This will allow us to compare indicators of social comfort and wellbeing as a function of intervention participation from both the child and cat's perspective.

3. Independent Responsibility Measure: We will use the 1-page Pet Care Responsibility Inventory [29] to evaluate changes in reported caretaking and responsibility for the family cat before and after intervention. We will also compare Pet Care Responsibility Inventory scores between the experimental and control group.

Sample Size Justification and Statistical Analysis Plan:

To determine the optimal sample size, we based our power analysis on effect size and noise level estimated using our preliminary data from our successful prior R21 dog training AAI study [R21HD091895]. To achieve at least 92% power for detecting an increase in the overall care and responsibility activities, the minimum sample size would be 10 per group, power increased to 99% with a sample size of 15. A sample size of 10 would also enable a power of 79% for detecting an increase in animal walking (physical activity measure), a sample size of 15 increased this to 93% power. However, we anticipate a higher level of attrition than in previous studies due to behavioral differences between cats and dogs. Therefore, for the proposed project, we will recruit 25 participants per group, which will provide the necessary power to detect statistical differences where they exist, even if attrition occurs. This sample size will also allow us to model the effects of covariates, such as age of participants, that could potentially influence the efficacy of the CAT intervention. Behavior will always be coded from video by two independent coders (blind to group assignment) to assess inter-rater reliability. Characterizing the cat-child bond will consist of holistic attachment style analysis from which proportions of dyads falling into different attachment classifications can be determined and included in efficacy analyses (Aim 1).

*Minor updates to statistical analysis plan post data collection

To assess efficacy of the CAT intervention we planned to conduct a survival analysis for program retention and for the population of cats reaching each milestone in the training program (Aim 2). However, our retention rate was high at 97% so no survival analysis was necessary. Cat milestones were analyzed as part of our fidelity analysis using non-parametric correlation tests appropriate for non-normal and/or non-continuous data (e.g., Spearman's Rank Correlation). To assess the effectiveness of CAT (Aims 2 & 3), we will perform paired t-tests, independent t-tests, linear regression and analysis of variance as appropriate to evaluate any changes in physical activity/joint walking, sociability (cat) and social wellbeing (child) scores, and HAI measures, for CAT participants across three assessment time points. We will also compare any improvement in the training group to changes within the control group. This study design allows us to evaluate the difference between the CAT intervention group and control group after accounting for baseline variability among child-cat pairs (see below). The incorporation of baseline data will reduce the noise level in our model and therefore enhance the statistical efficiency. For any data not conforming to the requirements of parametric tests (e.g., normality), we will use non-parametric tests such as McNemar's Test, Fisher's Exact test, etc.).A fully randomized control trial approach will be utilized. Block randomization will be conducted to ensure a balance in the sample size between groups

Modification Requested:

“After consultation and approval from our funder (NIH program officer), we propose to expand the participant age range in our study from 10-12 years to 8-17 years. This adjustment aligns with our original intention to explore the intervention efficacy in children with disabilities more broadly. We have successfully run AAI programs with 8–17-year-old children previously. The revision maintains our current procedures and assessments, ensuring no additional risk to our participants.”

HE-2022-29 - Modification

Date: September 13, 2023

PI: Megan MacDonald

Department: ASC - Animal & Rangeland Sciences, HHS - Public Health/Human Sci Admin

Re: Modification - HE-2022-29

The development and evaluation of a novel Cat Assisted Training (CAT) intervention for youth with developmental disabilities and their family cat.

The Oregon State University Institutional Review Board has rendered the decision below for *The development and evaluation of a novel Cat Assisted Training (CAT) intervention for youth with developmental disabilities and their family cat.*.

Decision: Approved

Category: 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Any modifications to the approved study must be submitted for review through Cayuse HE. All approval letters and study documents are located within the Study Details in Cayuse HE.

The above referenced study was approved by the OSU Institutional Review Board (IRB). The IRB has determined that the protocol meets the minimum criteria for approval under the applicable regulations pertaining to human research protections. The Principal Investigator is responsible for ensuring compliance with any additional applicable laws, University or site-specific policies, and sponsor requirements. Study design and scientific merit have been evaluated to the extent required to determine that the regulatory criteria for approval have been met [45CFR46.111(a)(1)(i), 45CFR46.111(a)(2)].

Cayuse Index Number: 22-0709

All previous determination and waivers still apply to this study. If any additional determinations were made as part of the review of this submission, they are listed below.

Risk Level determination: The IRB determined the research procedures described in this application constitute no more than minimal risks to subjects.

Consent: Consent is obtained in accordance with 45 CFR 46.116. Written consent is not required for eligibility screening procedures.

Child Risk Level and Category: The IRB determined that this research can be conducted under 45 CFR 46.404 as it involves no greater than minimal risk to child subjects.

Child Capacity to Assent: The IRB determined that the child subjects are capable of assent according to 45 CFR 46.408(a).

Assent: Assent is obtained in according to 45 CFR 46.408(a)

Parent permission: Parent permission is obtained in according to 45 CFR 46.408(b). **Documentation of Parent Permission:** Written parent permission will be obtained from all subjects' parents and for all procedures in accordance with 45 CFR 46.117.

Clinical Trial - This study meets the NIH definition of a clinical trial. The investigator must register this study on ClinicalTrials.gov no later than 21 days after enrolling the first subject. If you do not already have an account with ClinicalTrials.gov, one will be created for you. Once you have registered the study, you must update the record in ClinicalTrials.gov at least annually. If you amend the protocol in a way that impacts the information that you have entered into the ClinicalTrials.gov record, you are required to update that record within 30 calendar days after the amendment is approved by the IRB.

Notes to Researcher: Modifications to participant ages and recruitment flyer.

Principal Investigator responsibilities:

- *Keep study team members informed of the status of the research and ensure all team members follow the approved protocol.*
- *Obtain IRB approval for project revisions prior to implementing changes.*
- *Report all unanticipated problems involving risks to participants or others within three calendar days.*
- *Use only approved consent document(s).*

Sincerely,

Oregon State University Institutional Review Board

Modification requested:

“We request to increase the target enrollment from 60 to 100 participants. Our initial target enrollment was based on anticipated attrition levels derived from a similar study with children and dogs. However, we now anticipate attrition levels may be higher in this current group, due to behavioral differences between cats and dogs.

We have adjusted the language describing the intervention by changing "six week" program into "six session" program. This will provide scheduling flexibility/increased retention based on participant schedules. Total duration and all participant experiences remain the same.”

HE-2022-29 - Modification: Modification

Date: September 13, 2023

PI: Megan MacDonald

Department: ASC - Animal & Rangeland Sciences, HHS - Public Health/Human Sci Admin

Re: Modification - HE-2022-29

The development and evaluation of a novel Cat Assisted Training (CAT) intervention for youth with developmental disabilities and their family cat.

The Oregon State University Institutional Review Board has rendered the decision below for *The development and evaluation of a novel Cat Assisted Training (CAT) intervention for youth with developmental disabilities and their family cat.*.

Decision: Approved

Category: 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)Any modifications to the approved study must be submitted for review through Cayuse HE. All approval letters and study documents are located within the Study Details in Cayuse HE.

The above referenced study was approved by the OSU Institutional Review Board (IRB). The IRB has determined that the protocol meets the minimum criteria for approval under the applicable regulations pertaining to human research protections. The Principal Investigator is responsible for ensuring compliance with any additional applicable laws, University or site-specific policies, and sponsor requirements. Study design and scientific merit have been evaluated to the extent required to determine that the regulatory criteria for approval have been met [45CFR46.111(a)(1)(i), 45CFR46.111(a)(2)].

Cayuse Index Number: 22-0709

All previous determination and waivers still apply to this study. If any additional determinations were made as part of the review of this submission, they are listed below.

Risk Level determination: The IRB determined the research procedures described in this application constitute no more than minimal risks to subjects.

Consent: Consent is obtained in accordance with 45 CFR 46.116. Written consent is not required for eligibility screening procedures.

Child Risk Level and Category: The IRB determined that this research can be conducted under 45 CFR 46.404 as it involves no greater than minimal risk to child subjects.

Child Capacity to Assent: The IRB determined that the child subjects are capable of assent according to 45 CFR 46.408(a).

Assent: Assent is obtained in according to 45 CFR 46.408(a)

Parent permission: Parent permission is obtained in according to 45 CFR 46.408(b). **Documentation of Parent Permission:** Written parent permission will be obtained from all subjects' parents and for all procedures in accordance with 45 CFR 46.117.

Clinical Trial - This study meets the NIH definition of a clinical trial. The investigator must register this study on ClinicalTrials.gov no later than 21 days after enrolling the first subject. If you do not already have an account with ClinicalTrials.gov, one will be created for you. Once you have registered the study, you must update the record in ClinicalTrials.gov at least annually. If you amend the protocol in a way that impacts the information that you have entered into the ClinicalTrials.gov record, you are required to update that record within 30 calendar days after the amendment is approved by the IRB.

Notes to Researcher: Modifications to participant ages and recruitment flyer.

Principal Investigator responsibilities:

- *Keep study team members informed of the status of the research and ensure all team members follow the approved protocol.*
- *Obtain IRB approval for project revisions prior to implementing changes.*
- *Report all unanticipated problems involving risks to participants or others within three calendar days.*
- *Use only approved consent document(s).*

Sincerely,

Oregon State University Institutional Review Board

Bibliography & References Cited

1. Esposito, P. E., MacDonald, M., Hornyak, J. E., & Ulrich, D. A. (2012). Physical activity patterns of youth with Down syndrome. *Intellectual and Developmental Disabilities, 50*(2), 109–119. https://doi.org/10.1352/1934-9556-50.2.109

2. MacDonald, M., Esposito, P., & Ulrich, D. (2011). The physical activity patterns of children with autism. *BMC Research Notes, 4*, 422. https://doi.org/10.1186/1756-0500-4-422

3. Wenden, E. J., Lester, L., Zubrick, S. R., Ng, M., & Christian, H. E. (2021). The relationship between dog ownership, dog play, family dog walking, and preschooler social–emotional development. *Pediatric Research, 89*, 1013–1019. https://doi.org/10.1038/s41390-020-1007-2

4. Purewal, R., Christley, R., Kordas, K., Joinson, C., Meints, K., Gee, N., & Westgarth, C. (2017). Companion animals and child/adolescent development: A systematic review. *International Journal of Environmental Research and Public Health, 14*(3), 234. https://doi.org/10.3390/ijerph14030234

5. Vidović, V. V., Štetić, V. V., & Bratko, D. (1999). Pet ownership, type of pet, and socio-emotional development of school children. *Anthrozoös, 12*(4), 211–217. https://doi.org/10.2752/089279399787000129

6. Wanser, S. H., Simpson, A. C., MacDonald, M., & Udell, M. A. R. (2020). Considering family dog attachment bonds. *Frontiers in Psychology, 11*, 566910. https://doi.org/10.3389/fpsyg.2020.566910

7. Vitale, K. R., Behnke, A. C., & Udell, M. A. R. (2019). First evidence of secure attachment bonds between domestic cats and humans. *Current Biology, 29*, R864–R865. https://doi.org/10.1016/j.cub.2019.08.036

8. American Pet Products Association. (2018). *Pet industry market size & ownership statistics*. http://www.americanpetproducts.org/press_industrytrends.asp

9. Vitale Shreve, K. R., & Udell, M. A. R. (2015). What's inside your cat's head? *Animal Cognition, 18*, 1195–1206. https://doi.org/10.1007/s10071-015-0897-6

10. Kogan, L., Kolus, C., & Schoenfeld-Tacher, R. (2017). Assessment of clicker training for shelter cats. *Animals, 7*(10), 73. https://doi.org/10.3390/ani7100073

11. Vitale, K. R., & Udell, M. A. R. (2019). The quality of being sociable. *Behavioural Processes, 158*, 11–17. https://doi.org/10.1016/j.beproc.2018.10.026

12. Hart, L. A., Thigpen, A. P., Willits, N. H., Lyons, L. A., Hertz-Picciotto, I., & Hart, B. L. (2018). Affectionate interactions of cats with children having Autism Spectrum Disorder. *Frontiers in Veterinary Science, 5*, 39. https://doi.org/10.3389/fvets.2018.00039

13. American Pet Products Association. (2017). *Pet industry market size & ownership statistics*. http://www.americanpetproducts.org/press_industrytrends.asp

14. American Pet Products Association. (2019). *2019–2020 APPA National Pet Owners Survey*. https://www.americanpetproducts.org/

15. Turner, D. C. (2021). Unanswered questions and hypotheses about domestic cat behavior. *Animals, 11*, 2823. https://doi.org/10.3390/ani11102823

16. Tepfer, A., Ross, S., MacDonald, M., Udell, M. A. R., Ruaux, C., & Baltzer, W. (2017). Family dog-assisted adapted physical activity: A case study. *Animals, 7*(5), 35. https://doi.org/10.3390/ani7050035

17. Burgon, H. L. (2011). "Queen of the world": Experiences of 'at-risk' young people in equine-assisted therapy. *Journal of Social Work Practice, 25*(2), 165–183. https://doi.org/10.1080/02650533.2011.561304

18. Dinis, F. A. B. S. G., & Martins, T. L. F. (2016). Does cat attachment affect human health? *Pet Behaviour Science, 1*, 1–12. https://doi.org/10.21071/pbs.v0i1.3986

19. Thapar, A., Collishaw, S., Pine, D. S., & Thapar, A. K. (2012). Depression in adolescence. *The Lancet, 379*, 1056–1067. https://doi.org/10.1016/S0140-6736(11)60871-4

20. German, A. J. (2006). The growing problem of obesity in dogs and cats. *The Journal of Nutrition, 136*, 1940S–1946S. https://doi.org/10.1093/jn/136.7.1940S

21. Guinness World Records. (2021). *Most tricks performed by a cat in one minute*. https://www.guinnessworldrecords.com/world-records/391893-most-tricks-performed-by-a-cat-in-one-minute

22. Wanser, S. H., MacDonald, M., & Udell, M. A. R. (2021). Dog–human behavioral synchronization. *Animal Cognition*, *24,* 747–752. https://doi.org/10.1007/s10071-020-01454-4

23. Dorey, N. R., Conover, A. M., & Udell, M. A. R. (2014). Interspecific communication from people to horses. *Journal of Comparative Psychology, 128*(3), 337–342. https://doi.org/10.1037/a0037255

24. Bowlby, J. (1982). *Attachment and loss: Vol. 1. Attachment* (2nd ed.). Basic Books.

25. Wanser, S. H., & Udell, M. A. R. (2018). Does attachment security influence dog behavior? *Applied Animal Behaviour Science, 203*, 42–50. https://doi.org/10.1016/j.applanim.2018.09.005

26. Vitale Shreve, K. R., Mehrkam, L. R., & Udell, M. A. R. (2017). Social interaction, food, scent, or toys? *Behavioural Processes, 141*, 1–7. https://doi.org/10.1016/j.beproc.2017.03.016

27. Cameron Ponitz, C. E., McClelland, M. M., Jewkes, A. M., Connor, C. M., Farris, C. L., & Morrison, F. J. (2008). Touch your toes! *Early Childhood Research Quarterly, 23*(2), 141–158. https://doi.org/10.1016/j.ecresq.2007.01.004

28. Thompson, K. L., & Gullone, E. (2003). The Children's Treatment of Animals Questionnaire (CTAQ). *Society & Animals, 11*(1), 1–15. https://psycnet.apa.org/doi/10.1163/156853003321618800

29. Davis, J. H. (1987). Pet care during preadolescence. *Child Care, Health and Development, 13*(4), 269–276. https://doi.org/10.1111/j.1365-2214.1987.tb00543.x

30. Johnson, T. P., Garrity, T. F., & Stallones, L. (1992). Psychometric evaluation of the LAPS. *Anthrozoös, 5*(3), 160–175. https://doi.org/10.2752/089279392787011395

31. Duffy, D. L., de Moura, R. T. D., & Serpell, J. A. (2017). Fe-BARQ development. *Behavioural Processes, 141*, 329–341. https://doi.org/10.1016/j.beproc.2017.02.010

32. National Institutes of Health & Northwestern University. (2016). *Emotional support (ages 8–17).* *https://www.healthmeasures.net/index.php?option=com_instruments&view=measure&id=642&Itemid=992*