

Study Title:

Assessing mechanisms of anxiety reduction in animal-assisted interventions for

adolescents with social anxiety

NCT #03249116

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## Statistical Analysis Plan

### *Sample Size Calculation:*

To estimate the sample size, we used heart rate (HR) as the primary outcome and the STAI (state subscale) as the secondary outcome. There are no prior data with which to estimate the relative effect of the two intervention and control conditions on the proposed outcomes. Therefore, estimates were compiled from other research using HR as an indicator of stress response (e.g., Greenland et al., 1999). In this situation, the most conservative approach for sample size calculation is to assume a series of two-way tests. We used a mean of 75 beats per minute (bpm) with a  $SD$  of 12 bpm for baseline in all groups, assuming normal distribution, an equal number of subjects in each group, and a 0.05 significance level (alpha). With these assumptions, we will have 90% power to detect a difference of 12 bpm between any two treatment groups with 23 subjects per group, which we round to 25 per group for a total of 75 subjects in the three treatment groups. To determine the power for the STAI state subscale, based on the STAI normative data (Spielberger et al., 1983), we use a mean of 35.5 with a  $SD$  of 10.5. Using the same approach as above for HR, we will have 90% power to detect a difference of 10 between any two groups with a sample size of 25. All sample size and power calculations were performed using PASS 13 (Hintze, 2014).

### *Analyses:*

To test our confirmatory hypotheses, we conducted two three-way analyses of variance (ANOVA) with either self-reported anxiety (STAI), autonomic reactivity (electrodermal activity [EDA] and heart rate [HR]) as the dependent variable. For these outcomes, there were two between-subjects factors, condition (social, social + physical, control) and social anxiety (SA; centered continuous predictor), and one within-subjects factor, time point (1, 2, 3, 4, 5, 6). We included baseline STAI, EDA, or HR at time point 1 as a centered continuous covariate. For cognitive performance, we conducted ANOVAs that treated condition as a between-subjects categorical factor and social anxiety as a centered continuous predictor.