Study Protocol

Title: The Food Allergy Superheroes Training (FAST) Program: Increasing Adherence to Food Allergy Safety Guidelines

Identifier: NCT04400214

Document Date: 07/01/2019

1. Sample Size Determination and Power Analysis

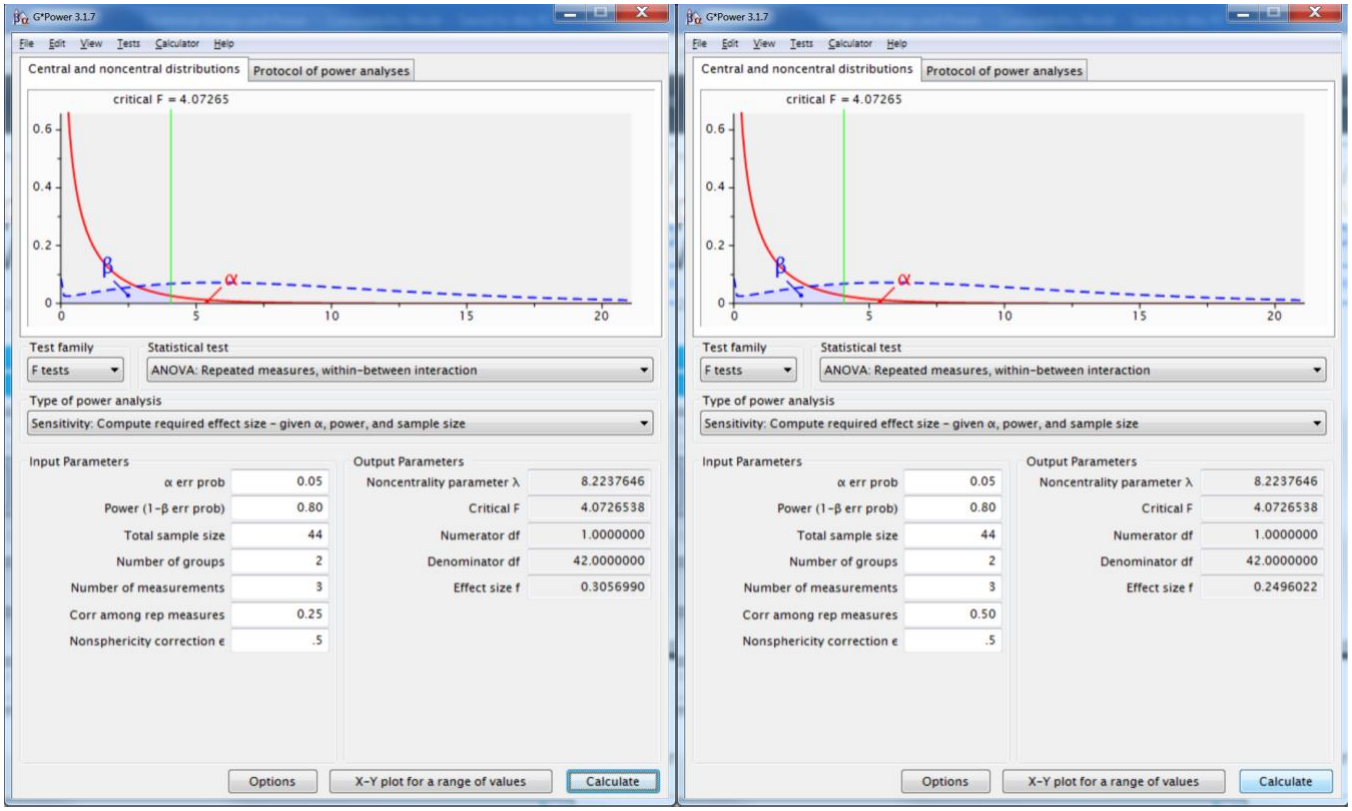
The primary aims of this study are to determine feasibility and acceptability of the FAST Program (**aim 1**) and to gather sufficient information to preliminarily estimate the effect size of the FAST Program relative to FA knowledge alone for a larger trial (**aim 2**). Given our teams' previous experience, we estimate that we will able be able recruit N = 50 (two groups of n = 25) and retain 88% (N = 44) at follow-up. As such, we computed the required effect size given alpha (0.05), power (.80), and sample size N=50 and, N=44 at follow-up. Given the primary outcome measures (coding scheme employed for child-report, role-play, and *in situ* FA assessments) yield ordinal data with unknown distributions, three options were considered to analyze the outcome data to address a variety of possible data distributions scenarios. Below is a summary, followed by associated figures:

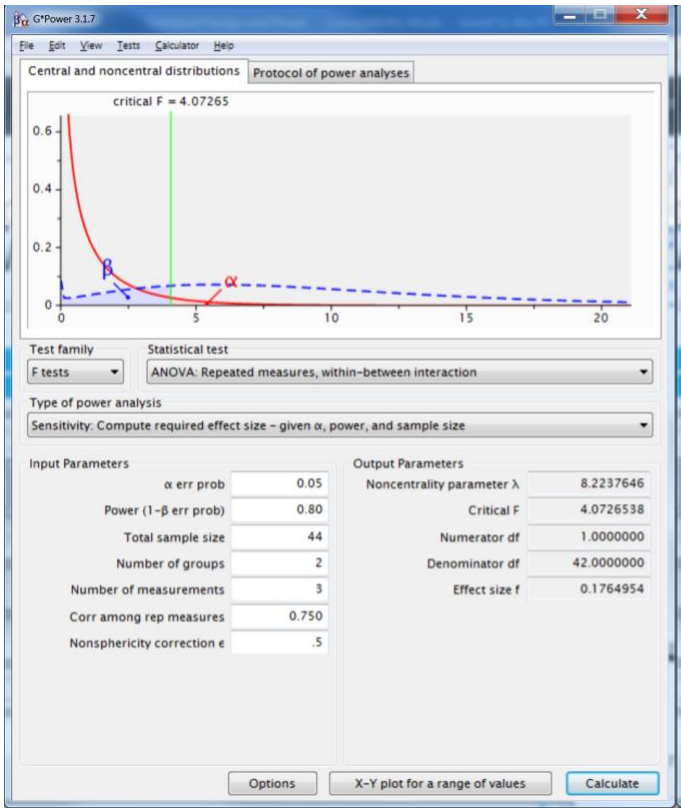
Summary:

- An approximately **medium size effect** (*f,* for within and between factor interaction) is detectable using traditional repeated measures ANOVA (*f* = .14 to .31 varying correlations among repeated
  measures: .25, .50 and .75; and nonsphericity corrections at 0.5 and 1), where *f* = 0.10, *f* = 0.25, and *f* = 0.40 are small, medium, and large respectively (p.348).[56]

- The non-parametric counterpart to this test can detect a **large effect size** (*d* = 0.88 to 0.93).

Supporting Figures

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Number of measurements 3
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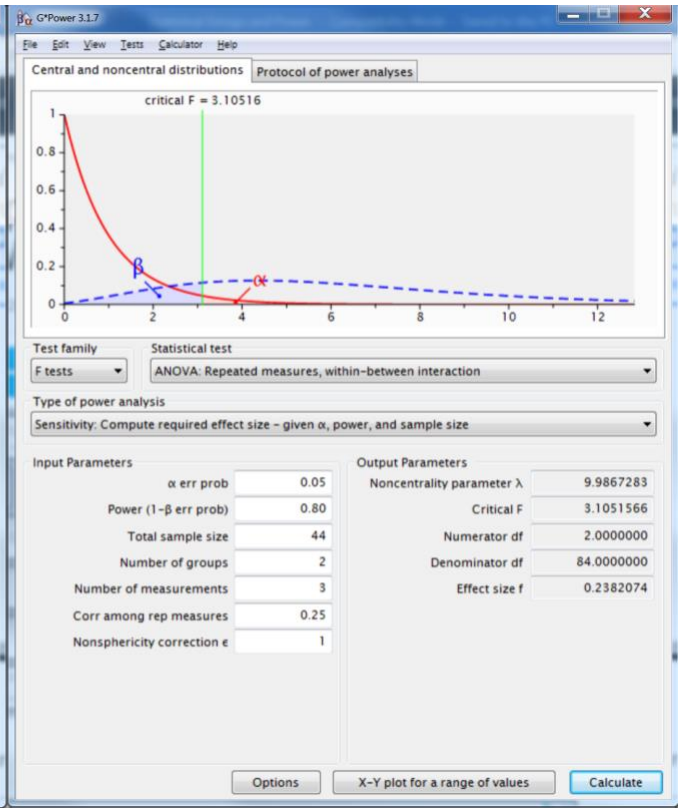
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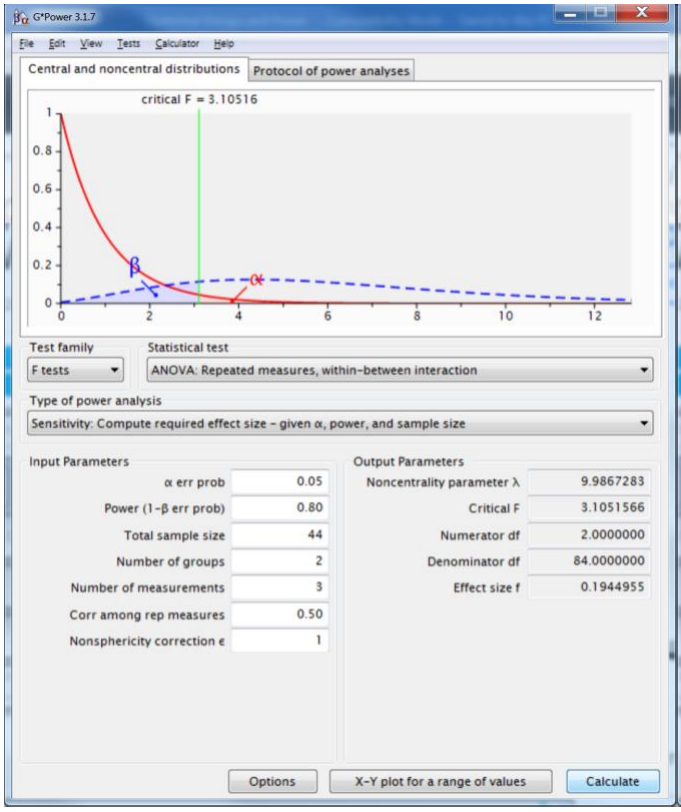
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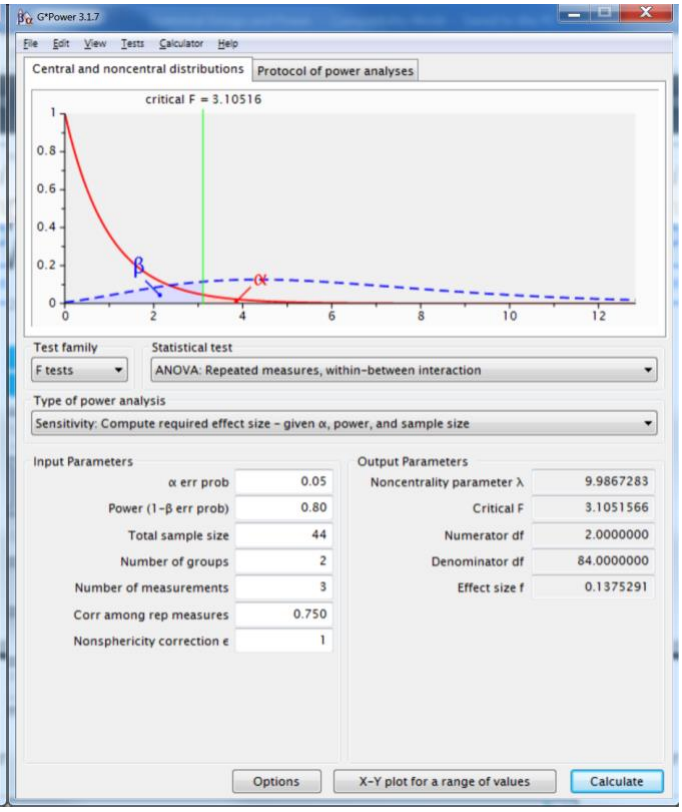
G*Power 3.1.7
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Protocol of power analyses
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Statistical test
ANOVA: Repeated measures, within-between interaction
Type of power analysis
Sensitivity: Compute required effect size – given α, power, and sample size
Input Parameters
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Power (1–β err prob) 0.80
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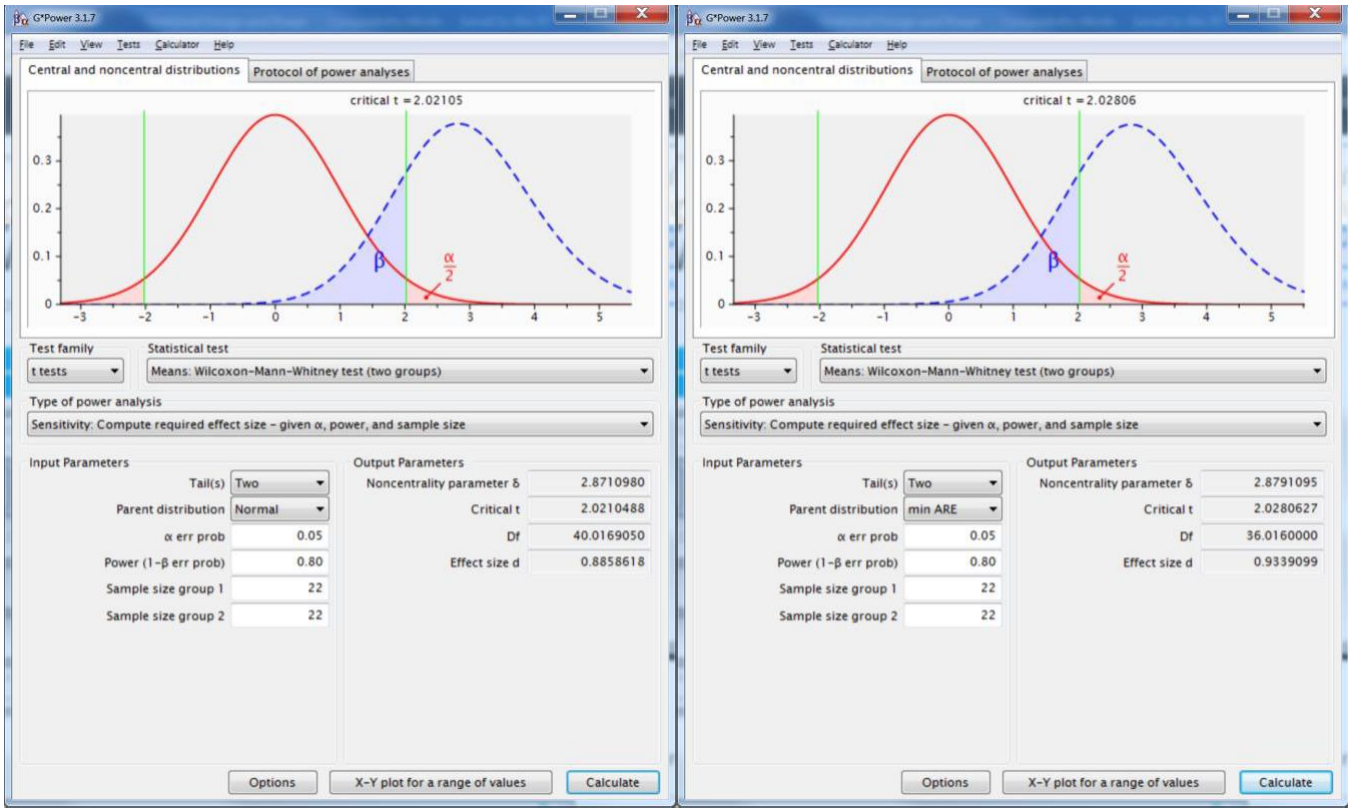
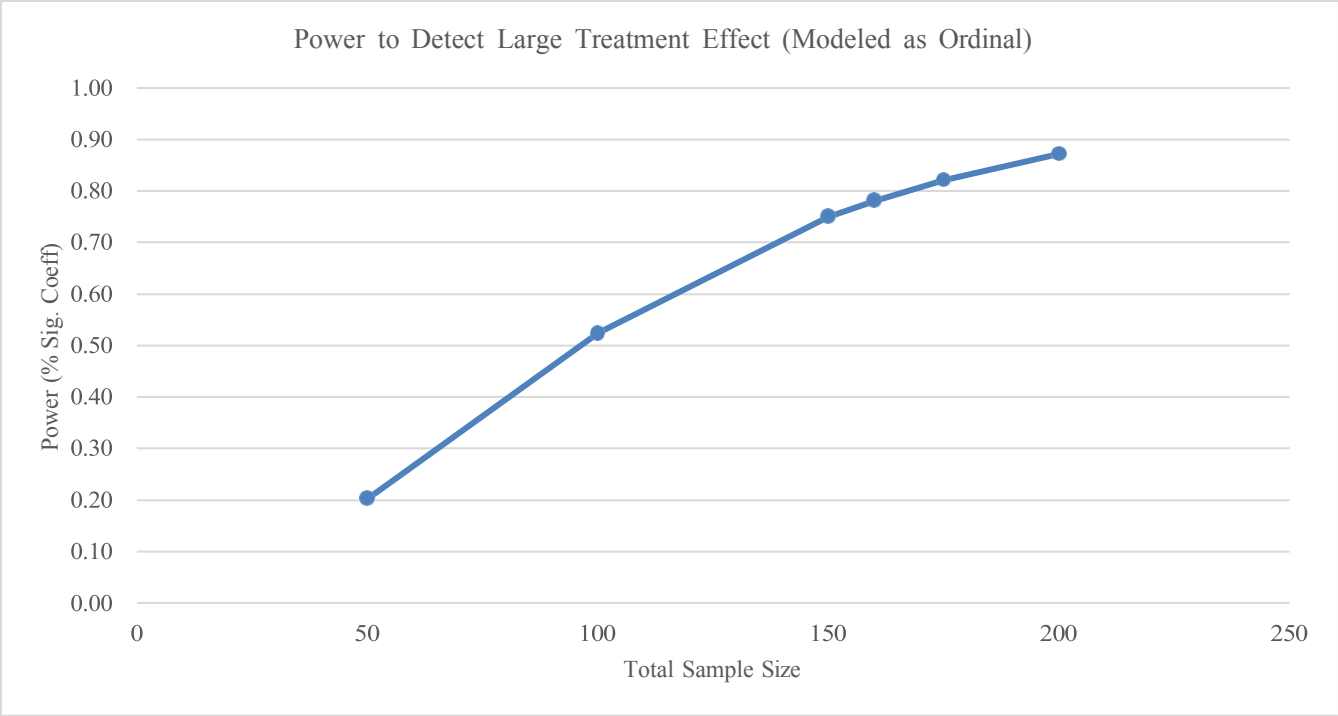
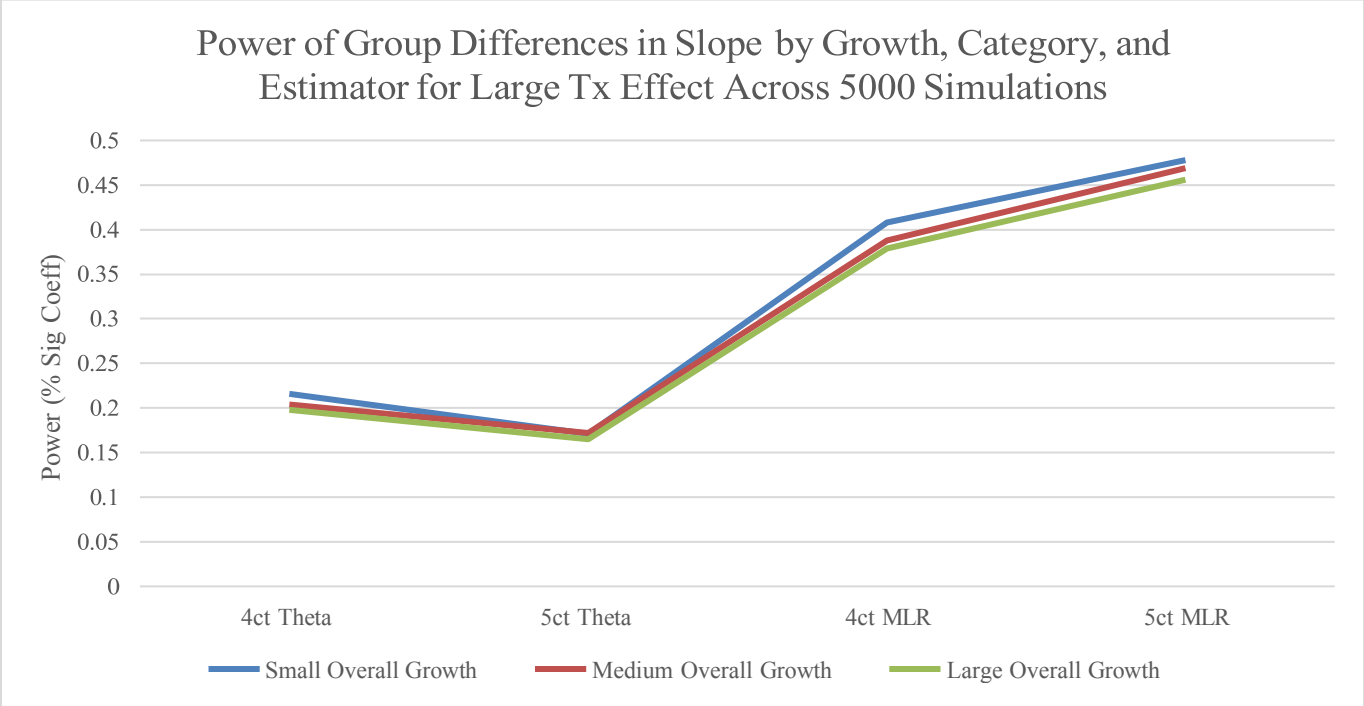


1.2 Alternative Analytic Strategies Considered and Sample Size Planning for Future Trials

We had initially considered using random effect growth modeling of piecewise growth; however, our preliminary Monte Carlo simulation suggested that only a very large effect size (d = 1.79) could be detected at this sample size. Additional simulations suggested sample size of ≈ 170 was needed to detect large group differences in slopes (d = 0.80). Here the effect size was computed as the ratio of the difference in the slope means across the conditions (covariate coded 0 and 1, M = .5, SD = .5) divided by the standard deviation of the slope growth factor (SD = .32).[57] We assumed "normal" threshold distributions for categories (Four Category thresholds: -1.25, 0, and 1.25; Five Categories: -1.50, -0.50, 0.50, and 1.50).[58] Piecewise growth across three timepoints was modeled using WLSMV estimation with theta parametrization (when considered ordinal) and robust maximum likelihood estimation (when considered continuous, allowing for non-normality, which can be appropriate given some scenarios).[58] We assumed growth intercept of M = 0, SD = 0.5, Time 1 to time 2 slope SD = 0.32; Time 2 to time 3 slope M = 0, SD = 0.32, and 88% retention at time 3. For the first slope, values were chosen to reflect overall (average) growth that was small (.2 SDs), medium (0.5 SDs), and Large (0.8 SDs). These simulations revealed that modeling the data as "continuous" (via robust maximum likelihood estimation) with either four or five categories (vs. ordinal with a WLSMV estimator) increased power by 0.2 to 1.9 times while maintaining adequate coverage (0.91 and 0.99), yet it was underpowered relative to other analytic strategies given our proposed sample size.

Supporting Figures





It is noted that our simulation made several conservative assumptions regarding the model parameters. Our plan is to use the data collected from this R21 to inform future sample size calculations to power random effect growth model, by providing some preliminary estimates of our variables' thresholds/intercepts (proportions/means), variances, and covariance, as well as those of the intercepts and slopes of the growth models across groups

Data Analytic Plan:**

Aim 1 (Phases 1a and 1b): Determine feasibility and acceptability of the FAST Program. We will evaluate the feasibility and acceptability of this intervention with 60 participants (*n*=10 in pilot trial [Phase 1a] and *n*=50 in a preliminary randomized trial [Phase 1b]). Descriptive statistics will be obtained for measures of retention through the 5-session intervention, via child- and parent-rated treatment acceptability, and in-depth closing interviews after each session (Phase 1a only).

Aim 2 (Phase 1b only, randomized trial): Estimate the effect size of the FAST Program relative to FA knowledge alone. Data will be analyzed: 1) according to the CONSORT criteria including intent-to-treat (ITT) analyses, which ensure a conservative estimate of treatment effects and avoids confounds of patient characteristics with treatment allocation. We will prioritize repeated measures ANOVAs given the greater power of these tests; however, if the skewness and kurtosis exceed z = 3.29, non-parametric analyses will be conducted.

To determine sample size for future trials, random effects piecewise growth modeling will be conducted in order to provide initial estimates for future simulation studies. More specifically these analyses will provide estimates of the following parameters which are needed to calculate power via Monte Carlo simulations: Outcome Thresholds/intercepts at each time period; means, variances, and covariances of the baseline intercept, slope 1 growth, slope 2 growth; and when modeled with group as a predictor: residual variances and covariances of intercept and slopes 1 and 2; estimates of intercepts and slopes regressed on group.

**The data analytic plan described herein represents our research team's original plan for analyzing data collected as part of this project. Due to the significant hinderance to recruitment resulting from the COVID-19 pandemic, the analyses described below were not possible (i.e., insufficient sample size to run statistical tests).