**Study Title: Services to Enhance Social Functioning in Adults with Autism Spectrum Disorders**

NCT#: NCT04788537

Document Date: 01/01/2020

# Statistical Analysis Plan

This statistical plan was developed with co-investigator, Warren Bilker, Ph.D., Professor of Biostatistics at the University of Pennsylvania. All Aspects of study design and data analysis will be supervised by Drs. Brodkin (PI) Bilker. Statistical analysis will be conducted using R software.

**Randomization:** The **50 participants** recruited will be randomly assigned to either treatment (TUNE In) group (**n=25**) or the control (treatment as usual) group (**n=25**), using block randomization with random block sizes (blocks of 4 and 6), carried out using STATA 2015 software.

**Blinding**: The research assistant who collected pre- and post-treatment assessment data, as well as Dr. Bilker, who persons data analysis, will be blind to participants' treatment group assignment.

**Outcome variables**: The primary outcome variable (SRS-2), as well as the exploratory outcome assessments (SRS-SR, Hinting Task, ER40, LSAS, CASS, SNI, and SPWB), will be conducted at enrollment and at the end of the study in both groups.

**Statistical analysis:** To test the effects of the treatment on SRS-2, we will use a mixed model regression, which is analogous to a repeated measures analysis of variance (RM-ANOVA) but allows for greater flexibility of the variance structure of the repeated measures than the RM-ANOVA. In the mixed model regression, we will include variables for time (pre vs post treatment), group (TUNE In vs Treatment as Usual), and an interaction between time and group.

**Power analysis:** Assessment of power and sample size was performed using PASS 15. The sample size determination was based on the observed pilot data (Figure 3). In order to detect a difference of 50% of the observed difference in the pilot data, with at least 80% power for all effects (group, time, and the interaction) and a type 1 error of 5%, 14 subjects per group are needed, based on a mixed effect regression model. We will recruit 50 participants (25 per group), to account for possible attrition from the study, and to ensure sufficient statistical power. We expect that at least 42 participants (21 per group) will complete participation in the study (accounting for the possibility of 10-15% attrition rate from the study, a maximal estimate based on our pilot study of TUNE In).