

**Expanding the Family Check-Up in Early Childhood to Promote Cardiovascular Health
of Mothers and Young Children (NCT05473767)**

Data Analysis Plan

University Of Pittsburgh IRB STUDY22020096 Approved 4/5/2022

As it is a pilot study, the focus will be on the estimation of the difference in mean levels of blood pressure and weight between women in FCU-Heart and FCU alone. Let δ be the intervention effect, representing the difference in mean BP and weight at 6 months between the two intervention arms. The mean difference δ will be estimated first by separately estimating the group means using observed sample means, and then taking a difference of the observed sample means. We will use two-sample t-distribution to construct a 95% confidence interval of the estimated δ to quantify the uncertainty in the estimation. The analysis will be repeated for each race stratum. With 100 participants in FCU-Heart and 50 in the standard FCU group, we will be able to estimate δ with a margin of error of 13.7% with 95% confidence, assuming a standard deviation of 40% in both populations. The sample sizes are sufficient to detect an effect size of 0.5 with 82% power at 5% level of significance. An effect size of 0.5 is consistent with intervention effects from the first early childhood FCU RCT on both parenting ($d=.48$) and child problem behavior ($d=.64$) 1-2 years post-intervention. Based on attaining 90% retention for the 6-month follow-up of the TPS-FCU study and our CVH intervention, we expect that our retention will also be ~90%. All the analyses will follow intention-to-treat principle (analyzed as randomized).