Study Title: Healthy Kids I-PAL
NCT #: NCT03297541
Document date: 08.24.17

Sample Size Justification

This protocol is a pilot & feasibility study that will provide data on acceptability, feasibility, and estimates of effect size for an R01 submission. A sample size of up to 30 dyads will provide sufficient data for feasibility and acceptability.

Planned Statistical Analyses

To determine if this mHealth approach to promote healthy behaviors and healthy weight among children and their parents will be utilized by parents of 6-10 year old overweight/obese children, descriptive statistics will be used to examine adherence and scores on the treatment acceptability and treatment satisfaction surveys. To obtain preliminary estimates of effect sizes, we will use mixed model analyses using an intent-to[1]treat approach. Model selection criteria using Akaike information criterion (AIC) will be employed to determine the best set of covariates, including, but not limited to, baseline demographic (e.g., sex, race) and anthropometric variables. T-tests based on the least squared means derived from the model are used to test the treatment effects. Responses such as change in body mass (kg and percent for the parents; BMIz for the children), physical activity, energy intake and diet quality, and treatment satisfaction and burden, will all be used in the mixed effect model and we will specifically include race and sex in the model to test if biological variables, such as sex, are associated with the outcomes.