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Study Title: Addressing Health Disparities in Childhood Obesity, One Summer at a Time

Clinical Trials Registration Number: NCT03595332

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Statistical Analysis Plan

The proposed statistical analyses for the current study includes a nested regression model utilizing Generalized Estimating Equations with an exchangeable working correlation matrix to account for the nested data structure of children within schools and families. For all variables, 95% Confidence intervals will be reported (for b in models with a linear response variable and Odds Ratios for models with an ordinal logistic response variable) and a significance level of $p=0.05$ will be used to test hypotheses.

For the primary analysis, we propose to test the difference in Body Mass Index (BMI) Percentile-scores for age and sex based on Centers for Disease Control and Prevention (CDC) criteria from Baseline to 10-weeks using GEE models with a linear response variable. We will test whether the difference is significantly different from zero, adjusting for age (included as a covariate) and sex and ethnicity (included as factors). We will also test whether the immediate intervention group was significantly different from the delayed intervention group by including a variable denoting immediate vs delayed group membership. We will test the null hypothesis that participants in the intervention did not significantly change their BMI Percentile-score.

For the second primary analysis, we will test whether the BMI Percentile from baseline to 10-weeks was significantly different from zero among the highest-risk children, defined as those participants with a baseline BMI Percentile score equal to or greater than the 85th percentile as considered by the Centers for Disease Control and Prevention. GEE models will be used restricting the sample to children with overweight at baseline.

For the first secondary analysis, we propose to test the difference in Body Mass Index Percentile-score from Baseline to 1-year follow-up using GEE models with a linear response variable. We will test whether the difference is significantly different from zero, adjusting for age (included as a covariate) and sex and ethnicity (included as factors). We will test the null hypothesis that participants in the intervention did not significantly change their BMI Percentile-score.

For the additional secondary analyses, we propose to test the difference in average self-efficacy score (1-5) from Baseline to 10-week follow-up using GEE models with an ordinal logistic response variable. We will test whether the difference is significantly different from zero, adjusting for age (included as a covariate) and sex and ethnicity (included as factors). We will test the null hypothesis that participants in the intervention did not significantly change their average self-efficacy score.