

Title: Preventing Weight Gain and Unhealthy Behaviors in Children

08/08/2019

D8. Power Considerations, Statistical Design, and Missing Data. The SDM Core assisted the PI with respect to the analytic plan described in this application. The SDM Core will assist the research team with the codebook (for raw data and constructs), specification of missing data flagging and procedures, data entry/capture, data management, preliminary examination of distributions in preparation for analyses, conduct of statistical analyses, and assistance in interpretation of programming output. All analyses will be completed by the SDM Core which will have individuals with extensive expertise in the statistical models required for analyzing the data collected in the proposed project.

D8.1. Power Considerations. The power analysis was performed using G*Power (v.3.1.7) to determine the smallest effect detectable assuming a sample size of 80 participants, power of 0.80, correlation between measures of 0.80, and alpha of 0.05. The study is sufficiently powered to detect a Cohens *d* effect size of 0.20, considered a small effect. Previous large scale longitudinal studies of school year vs. summer weight gain,[12, 14, 36] studies that have provided a structured program to children during the summer,[129, 130] and pilot work have shown that the Cohens *d* effect size of the difference between conditions should be approximately 0.50. Children not receiving the Voucher Program are estimated to experience a mean increase in z-BMI of 0.22 over the summer. Conservatively, children in the Voucher Program are estimated to experience half of the gain in z-BMI during the summer of children not in the Voucher Program (i.e., 0.11 increase in z-BMI). The difference between z-BMI change for children who receive a voucher and do not receive a voucher (i.e., 0.22 vs. 0.11) is equivalent to a Cohens *d* of 0.46. However, the power to detect a small effect was chosen to ensure that the study is able to detect the effect of the primary and secondary outcomes.

D8.2. Statistical Models. To test the Aims, analytical modeling that capitalizes on the richness of the data set will be utilized. To test the hypothesis in Aim 1, repeated measures linear and non-linear mixed models accounting for repeated measures within children and children within schools will be estimated. Group, time, setting (i.e., school vs. summer) and all 2-way and 3-way interactions will be included, with the group-x-time-x-setting interaction as the primary contrast of interest. For Aim 2, the differences in obesogenic behaviors over time will be evaluated using the same repeated measures linear and non-linear mixed models. Structural equation models will be estimated to evaluate the mediating pathways of the obesogenic behaviors on the amount of change occurring in zBMI over time between the two groups.

D8.3. Sex as a Biological Variable. Because girls and boys have been shown to engage in differing levels of obesogenic behaviors and to have differing levels of fitness and prevalence of overweight and obesity, all models will include sex (i.e., boys vs. girls) and age as covariates. Including sex as a covariate in models will preserve the statistical power of the study while allowing for the examination of sex as a biological variable.

D8.4. Missing Data. Across this study, four scenarios with missing data are possible: 1) missing items within children; 2) missing cases (i.e., children not present to complete assessments); and whether the missingness is for 3) missing determinants/covariates or 4) missing outcomes (e.g., zBMI, physical activity). For missing assessments, such as incomplete diaries, parent surveys, accelerometer data, or BMI, the parents will be contacted and, where willing, they will be invited to re-complete the missing assessments. Where children are not present at the school on days of BMI assessments or to pick-up their monitor and surveys, data collectors will return to the camp on another day to complete the assessments. For any assessments not obtained, models will be estimated using full information maximum likelihood estimators, as well as employ multiple imputation techniques. These two strategies for handling missing outcome data will be compared (analogous to a sensitivity analysis) to determine the most appropriate way to handle the missingness. Based on previous large-scale group randomized trials,[102, 131] full information maximum likelihood estimators provide a robust and unbiased estimate. This is consistent with literature comparing this estimator to models using multiple imputation.[132] For missing determinant/covariates that are continuous, multiple imputations will be employed. For missing determinant/covariates that are categorical, a missing dummy variable technique will be used rather than imputing categorical data.[133, 134]