

Title: School Nurse-directed Secondary Obesity Prevention for Elementary School Children  
NCT#: 02029976  
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### Statistical Analyses

The primary outcome, child BMI-z at post intervention, was compared between intervention and control groups using general linear mixed model controlling for a blocked partially clustered design (intervention group only) via a random effect, adjusting for baseline BMI-z, child age, sex and puberty scale. Model diagnostics included assessment of conditional standardized residuals, normal probability and quantile-quantile plots and influence diagnostics using graphical procedures and influence statistics. Child BMI-z at follow up and percent body fat at post-intervention and follow-up were modeled in similar manner as the primary outcome. A priori power analyses estimated a minimal detectable treatment group effect size of 0.25 for age- and sex-adjusted BMI-z at 80% power with a sample size of 114 children or 57 per treatment group.

An adjustment for the partially clustered design was not performed for dietary and activity outcomes given small realized cluster sizes within the intervention group. The Healthy Eating Index, added sugars, energy, fat and saturated fat were modeled using general linear models; fruit, vegetable, fruit and vegetable juice and sugar-sweetened beverages were analyzed using marginalized two-part models; all models adjusted for baseline value, child percent body fat, sex and economic assistance. Sedentary and physical activity outcomes were modeled using generalized linear models (beta regression) adjusting for baseline value, child percent body fat, sex and age.

A two-sided type I error rate of 5% and 95% confidence intervals were used to assess statistical significance. For secondary outcomes, no adjustment for multiple comparisons was performed as analyses were considered supportive of the primary analysis and exploratory in nature. No modifications or imputations were made to the database, with the exception of accelerometer data. SAS software 9.4 (SAS Institute Inc., Cary, NC, USA) and R software were used.