Healthy Hydration Pilot in Elementary Schools

NCT06132763

05/07/2025

D. POWER/ANALYSIS PLAN. Students, the unit of analysis, are nested within schools. Thus, we have a cluster RCT with 2 clusters (intervention and control school). To detect a 10% mean difference in water bottle usage between groups, with a common SD of 15, an unadjusted sample size of 17/group would be needed. Adjustments to this sample size were made using a variance inflation factor (based on the assumption of an ICC of .03) to accommodate homogeneity within the clusters. Using this assumption, 2 clusters of average size of 200 is sufficient to detect the hypothesized difference at α=.05 (two-sided) and a desired power of 80%. Thus, our proposed sample will be more than adequate to evaluate study aims. Contingency tables and frequency distributions will be evaluated and descriptive and inferential statistical analysis applied. Differences between schools in % of students with water bottles, hydration station counts (per student), % of students with SSBs at lunch, and beverage intake (BEV-Q; SSB, water, milk) will be evaluated using chi-square analysis. Difference between baseline and post values on these study outcomes will indicate an intervention effect, with one-way ANOVA conducted to test group differences. We will also graphically examine monthly trends in hydration station usage by school. Paired t-tests will examine differences in these outcomes by school. We will also examine interrater reliabilities (Kappas) among dental assessors and report baseline and post body mass index (BMI, BMIz, BMI percentile) and dental caries status (ICDAS criteria), as well as any observed differences by school over time (although none are expected in this study duration) to inform methods applied in a future trial. Descriptive statistics will be applied to examine trial feasibility (e.g., recruitment, retention, satisfaction, and implementation). Triangulating all data sources will be the basis for deriving final conclusions and recommendations for our future intervention.