A cluster randomized controlled trial of an after-school playground curriculum intervention to improve children's physical, social, and emotional health: Study protocol for the PLAYground project

NCT ID not yet assigned

Date: June 20, 2022

Statistical Analysis Plan

Data analysis

Intervention effects on the primary trial outcomes (at each follow-up time point) will be assessed using general linear mixed effects models to account for the clustering of individual measurements within schools. These will include fixed effects for treatment group (intervention vs control), time (baseline and follow-up), and interaction term (intervention x time); include school as a random effect; and be adjusted for covariates related to the outcome (eg, student sex, age). Analyses related to physical, social, and emotional health will be performed with the child (nested within a school) as the unit of analysis. Analysis related to attendance and behavioral change will be performed with the school as the level of analysis. Separate analyses will be performed at each follow-up time point. Schools will be included in analyses if they meet at least 80% adherence to the protocol.

Secondary implementation outcomes will be assessed using descriptive statistics for Healthy Staff and Student survey data (appropriateness and feasibility) and data from monthly observations (fidelity and sustainability). Frequencies, means, and standard deviations will be calculated to describe the distributions, measures of central tendency, and dispersion of item responses. Data from Healthy Staff and Student interviews will be analyzed using a matrix analysis to summarize and organize data in alignment with Proctor's dimensions (adherence, exposure/dose, quality of delivery, component differentiation, and participant involvement), and content analysis to identify salient themes for each school, by school-level income, and collectively among intervention school groups. We will utilize a deductive approach, but allow for additional themes to emerge.

Sample size calculation

The average enrollment of schools in the study district is 610 students. The average enrollment in all 14 after school programs across schools in the study district is 420 students. Using an estimate of a 70% participation rate among after-school programs and assuming 20% loss-to-follow-up, a sample of 7 intervention and 7 control schools will provide a sample of approximately 294 students (147 intervention and 147 control) at follow-up. Assuming an intra class correlation coefficient of 0.05 with 80% power and an alpha of 0.05, the sample will be sufficient to detect an effect size of .370, similar to other school-based PA interventions reporting small overall effects.