Kids SipSmartER, an Intervention to Reduce Sugar-sweetened Beverages

Statistical Analysis Plan

NCT#: NCT03740113

Date: 06/07/2019

Statistical Analysis Plan

Excerpted from protocol manuscript:
Zoellner JM, Porter KJ, You W, Chow PI, Ritterband LM, Yuhas M, Loyd A, McCormick BA, Brock DJ. Kids SIPsmartER, a cluster randomized controlled trial and multi-level intervention to improve sugar-sweetened beverages behaviors among Appalachian middle-school students: rationale, design & methods. Contemporary clinical trials. 2019 Aug 1;83:64-80.

Power calculation and sample size

Given the lack of interventions and designs similar to Kids SIP*smart*ER,[1] data from the Kids SIP*smart*ER feasibility study were used to estimate the effect size and intraclass correlation (ICC) of students' SSB intake.[2] Considering the school size eligibility criteria and anticipated variation in the number of students per school (range 80-200 students, average 133 students), a lower and upper range of power is estimated. Due to the cluster-randomized block design (i.e., randomization at school level), no attrition at the school level is anticipated. The sample size calculations are conservatively based on a small 7-month effect size of 0.3, a 0.05 type I error, and a 0.01 ICC of students' SSB intake. To achieve 80% power under these assumptions, a total of 12 schools/clusters (6 schools per condition) are needed, with 54 enrolled students per school (and 49 retained after an anticipated 10% attrition rate at student level at 7-month). Following these same assumptions, 99.99% power would be achieved with a total of 12 schools/clusters and an average of ~115 students enrolled per school (and 104 retained after an anticipated 10% attrition rate). In sum, using conservative effect size and ICC estimates and standard type I error rate, enrolling a minimum of 54 students and up to 115 students per 12 schools/clusters would provide adequate power ranging from 80% to 99.9% for the primary 7-month SSB student outcome.

Data analysis

Effectiveness analysis will be on the individual level. Due to the high degree of homogeneity (in income and race) among the eligible schools, focus will be placed on detecting potential selection bias on the individual level program participation and attrition. Appropriate descriptive, parametric, and non-parametric statistical methods will be used to compare continuous and categorical variables among the intervention conditions at baseline. Data will be examined for the presence of outliers, violations of normality for continuous variables, and missing data. Major violations of normality will be corrected with an appropriate transformation procedure. All analysis will use cluster-robust standard error adjustment.

Primary effectiveness aim

Multi-level mixed effect models will be used to control errors of non-independence and heteroscedasticity caused by individual, class and school heterogeneity, and potential covariates identified a priori based on the literature and theory that are relevant to SSB behavior changes.[3, 4] The treatment effect models used in this study will contain outcomes of interest as dependent variables (e.g., SSB kcal, quality of life measures etc.). Specific mixed effect link function will be chosen to fit different outcome distributions. The models will control those unobserved effects that are fixed over time at three different levels (i.e., individual student, class, and school) and those unobserved time and block fixed effects that are individual-class-school-invariant. To further examine intervention treatment effect differences across blocks, we will modify the models to allow group indicator to interact with time-block fixed effects.

Secondary effectiveness, maintenance and reach outcomes

The analytical model for the primary aim will be modified to assess these aims by making the secondary student outcomes the dependent variables. For nonlinear outcomes, such as discrete health literacy classification, appropriate link functions will be used in the multilevel model. Also, the time indicator in the model will be changed to examine effectiveness at 3-month, 7-month, and 19-month. For caregivers' outcome analysis, a simplified version of the above multilevel mixed effect selection models will be applied, recognizing the class nesting will not be of concern for this level. Furthermore, an additional indicator that signals the uptake of the SMS will be added to the model to examine the adoption of SMS influence on caregivers' behavior and home environment changes. To further explore student-caregiver dynamics, mixed effect structural equation models will examine the causal relationship among caregiver and student SSB outcome changes. Finally, differences in student effectiveness data will be explored by comparing student level changes within schools when Kids SIP*smart*ER is co-delivered by researchers-teachers versus when delivered by teachers only.

The program reach at student and caregiver levels will be analyzed following recommendations of Glasgow and colleagues.[5] Participation rate at each school will be determined by dividing the total number of 7th grade students and caregivers enrolled by the total number eligible to enroll. Representativeness will be assessed by comparing demographics of students and caregivers eligible and enrolled to the demographic data provided by schools. Uptake/utilization of SMS among caregivers will also be analyzed.

References

1. Lane H, Porter K, Estabrooks P, Zoellner J. A systematic review to assess sugar-sweetened beverage interventions for children and adolescents across the socioecological model. *Journal of the Academy of Nutrition and Dietetics*. 2016;116(8):1295-1307. doi:10.1016/j.jand.2016.04.015
2. Lane H, Porter K, Hecht E, Harris P, Zoellner J. Kids SIPsmartER: a feasibility study to reduce sugar-sweetened beverage consumption among middle school youth in Central Appalachia. *American Journal of Health Promotion*. 2018;32(6):1386-1401.
3. Laird N, Ware J. Random effects models for longitudinal data. *Biometrics*. 1982;38(963-74)
4. Murray D. *The Design and Analysis of Group Randomised Trials*. Oxford University Press; 1998.
5. Glasgow RE, Klesges LM, Dzewaltowski DA, Estabrooks PA, Vogt TM. Evaluating the impact of health promotion programs: using the RE-AIM framework to form summary measures for decision making involving complex issues. *Health Educ Res*. Oct 2006;21(5):688-694. doi:10.1093/her/cyl081