Official Title: Investigating Withdrawal Symptoms as Barriers to Reducing Sugar-sweetened Beverage Consumption among Children

NCT #: Not yet assigned

Date: July 15th, 2019

Statistical Design and Power

The primary purpose is to evaluate primary the feasibility of the intervention and therefore, formal sample size calculations for clinical outcomes were not performed. We will enroll a total of 60 participants (n=20 per group).

This study includes an intervention to remove caffeinated SSBs and to explore whether caffeinated SSB removal induces withdrawal symptoms in 8-11 year old (3rd-5th grade) children. Child participants in the clinical pilot study will be randomly assigned to replace their usual caffeinated SSB consumption with either caffeinated SSBs provided by the study team, caffeine-free SSBs or unsweetened sparkling water (also provided by the study team) for two weeks.

Caffeine withdrawal scores will be collected using caffeine withdrawal symptom questionnaires (CWSQ, completed by the child and parent together). Peak withdrawal symptoms will be operationalized as CWSQ scores reported within the initial 72 hours of the intervention, between the three groups. Univariate analyses and one-way ANOVA will be used to assess group differences in our primary (measures of compliance with beverage intervention) and secondary (withdrawal symptoms) study outcomes.

Compliance with beverage consumption will be assessed using beverage/compliance logs (completed by the parent and child together). We will operationalize compliance as the number of days in which participants consumed the study beverages, the total number of study beverages consumed during the intervention period, as well as any consumption of caffeinated SSB, juices etc. (in violation of the study protocol). Importantly, participants are being instructed simply to consume the study beverages in the same manner that they would normally consume their usual caffeinated sugar-sweetened beverages. They will not be assigned to consume a certain number of study beverages, simply to replace their usual beverages with the study drinks and to consume only the study drinks and water throughout the intervention period.

Liking of study drinks may affect compliance and we will therefore run exploratory multivariable linear regression models including taste ratings as a potential confounder, along other potential covariates such as sex, race/ethnicity, age, weight, and volume of habitual SSB consumption. While we recognize that we are not sufficiently powered for multivariable regression models including a large number of covariates, these data will be critical in informing sample size calculations for our subsequent R01 proposal. We will use an intention to treat (ITT) approach and will minimize loss to follow-up by maintaining close contact with participants. All analyses will be conducted using SAS 9.4.

Dietary intake will be collected through dietary recall interviews (completed by the parent and child together). This will allow us to assess adherence to the study beverages as replacements for habitual caffeinated SSBs and to determine if caffeinated SSB removal impacts dietary choices. While we acknowledge limitations inherent to self-report dietary assessment, dietary recalls are sufficient for capturing beverage consumption data and will enable us to determine whether participants change their diet to compensate for caffeine restriction.