RESEARCH PROTOCOL
Required Elements

TITLE: Investigating withdrawal symptoms as barriers to reducing sugar-sweetened beverage consumption among children: pilot intervention study

IRB #: NCR191271

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RESEARCH PLAN

A. Specific Aims

Specific Aims and Hypotheses:

1. Examine the feasibility of removing caffeinated sugar-sweetened beverages (SSB) from the child diet. We hypothesize that caffeinated SSB avoidance will be feasible among children, but that compliance will be lowest among those assigned to sparkling water, devoid of both caffeine and sugar. Compliance with beverage assignments will be assessed using daily online questionnaires and weekly dietary recalls.

2. Explore the extent to which caffeinated SSB removal induces withdrawal symptoms. We hypothesize that replacement of caffeinated SSBs with caffeine-free SSBs, or sparkling water will induce withdrawal symptoms compared to control (usual caffeinated SSB consumption). Participants will complete a child-adapted version of the validated Caffeine Withdrawal Symptoms Questionnaire (CWSQ) at baseline and daily (online) during the intervention.

B. Background and Significance

Sugar-sweetened beverages (SSBs) significantly contribute to sugar and calorie intakes, and their consumption is associated with metabolic disease.[1] Sweetened beverages also account for the majority of pediatric caffeine consumption.[2] It is well-established that habitual caffeine use leads to dependence in adults[3] and evidence for sugar dependence has been documented.[4] However, caffeine and/or sugar dependence related to sweetened beverage consumption has not been evaluated, and determinants of their consumption among youth are severely understudied. It is critical to elucidate whether they may be physiologically or psychologically dependent on these beverages, particularly SSBs, which contain both caffeine and sugar.

The purpose of this pilot study is to replace caffeinated SSB's with either caffeinated SSBs provided by the study team (control) or with caffeine-free and unsweetened alternatives (also provided by the study team) for 2 weeks, among children who habitually consume caffeinated SSBs.

Lowering SSB consumption is a central component of lifestyle behavior change aimed at preventing and managing obesity,[5] yet effective reduction of SSB intakes has been met with many challenges.[6] While their palatability, accessibility, publicity, affordability, and social acceptability contribute to frequent and sustained SSB consumption, their *caffeine and sugar content may further encourage continued intake.* Although adverse health consequences of excessive SSB consumption are well documented[7], the extent to which their pleasant taste (due primarily to their sugar content) and post-ingestive effects (due to their sugar and/or caffeine content) positively reinforce consumption among children has not been elucidated. *It is particularly important to understand the determinants of caffeinated SSB use in children because beverage consumption habits in childhood will likely be sustained into adolescence and adulthood and will contribute to obesity and metabolic disease risk later in life.* This is particularly important to study among children from low-income and minority backgrounds, as these children have the highest rates of SSB intake and the highest prevalence of obesity.

Examining the feasibility of removing caffeinated SSBs and exploring whether this induces withdrawal symptoms among youth will enable us to investigate independent and combined effects of avoiding sugar, caffeine, or both, which will be integral to the design of a future larger scale intervention and to inform ongoing and future efforts for reducing SSB consumption. Findings will provide a comprehensive picture of the extent to which children are dependent on sugar and/or caffeine in SSBs and will inform whether their removal is feasible. If withdrawal symptoms are observed, this will have important implications for future efforts to limit consumption.

C. Preliminary Studies

Not applicable.

D. Research Design and Methods

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) male and female children residing in the Washington, D.C. area. We expect that half of our total sample will be comprised of boys (n=30) and half of girls (n=30). Children under 8 are being excluded because of a lack of cognitive ability to fully understand the study components and their potential inability to complete study requirements that take place outside of the presence of the GW researchers. We are specifically recruiting children 8-11 years old because compared to older children/adolescents, this age range generally is under greater parental supervision and thus, these children are more likely to

comply with the intervention. We plan to study older children/adolescents in a future study. We will not exclude subjects on the basis of race/ethnicity and we anticipate that our study sample will be distributed proportionally to the race/ethnic distribution of the greater Washington metropolitan area, from which we will recruit. This research topic pertains to children from all race/ethnic backgrounds.

For the pilot intervention study, the primary purpose is to evaluate the feasibility of the intervention and therefore, formal sample size calculations for clinical outcomes were not performed.

Eligible children will be identified through community organizations (e.g. camps, after school programs, schools) and word of mouth. The child will be provided with study information by Dr. Meni and a trained research assistant (RA) on site. After obtaining informed consent (parent/guardian(s)) and assent (child), child volunteers will complete a screener questionnaire to determine initial study eligibility. Eligible and interested participants will be scheduled for a baseline visit, either at the Milken Institute School of Public Health or at a community location (e.g. community center, library) convenient to the participant.

Beginning at the baseline visit (in person) and continuing daily throughout the intervention (online), participants will be asked to complete a child-adapted version of the validated Caffeine Withdrawal Symptoms Questionnaire (CWSQ). During the baseline visit, child participants will taste a small sample of each study beverage in pairs and will rate which beverage they like better and which beverage tastes sweeter using the enclosed beverage taste testing form. Child participants will be randomized into one of three study arms, where they will be instructed to replace their usual caffeinated SSBs with either: caffeinated SSB's provided by the study team, caffeine-free SSBs (caffeine-free Pepsi) or unsweetened sparkling water (LaCroix), compared to control (regular Pepsi consumption) for two weeks. All beverages will be provided by the study team, including drinks for the control group. After randomization, participants (child and parent together) will complete a daily online compliance questionnaire.

An outline of the schedule of study activities is below:

Time	Activity
Baseline Study Visit (Day 0) 1.5 hours	• Consent/assent • Height and weight • Complete in-person Caffeine Withdrawal Symptoms Questionnaire (CWSQ) with parent and child [this is called Daily Feelings Questionnaire in the Assent Form for kid-friendly language] • Dietary recall (parent and child)

	• Beverage taste testing (child) • Randomization and counseling regarding intervention (parent and child) • Provision of study beverages
Intervention (Days 1-14) Total of 1 hour per week	• Parents receive three times weekly text message/email/phone reminders (based on participant preference) from study team • Parent and child together complete daily online CWSQ • Parent and child together complete daily online compliance survey • Child participant consumes assigned study beverages
Mid-intervention Visit Or Telephone Check-in (after first week of intervention) ~30-45 minutes	• Complete in-person Caffeine Withdrawal Symptoms Questionnaire (CWSQ, parent and child together) • Dietary recall (parent and child together) • Provision of additional study beverages if needed • Participants and their parents encouraged to ask questions or express concerns
Follow-up visit (Day 15) 1.5-2 hours	• Complete in-person Caffeine Withdrawal Symptoms Questionnaire (CWSQ, parent and child together) • Dietary recall (parent and child together) • Beverage taste testing (child participant) • Return empty study beverages • Qualitative interview (~20 minutes, parent and child together)

Details of all study procedures are described below:

Study Procedure	Description
Height and weight	Child participant's height and weightwill be measured using a portable scale and stadiometer.
Caffeine Withdrawal Symptoms Questionnaire (CWSQ)	Parent and child participants will together complete a child-adapted version of the validated CWSQ[8] in person at baseline, and online daily throughout the intervention. Dr. Meni and/or a trained RA will assist with CWSQ completion at baseline and will counsel participants regarding filling out the online questionnaire.
24 hour dietary recalls	Participants will be asked (with the help of their parent) to report everything that they eat and drink over the past 24 hours. 24-hour recalls will be conducted at baseline (in person), after 1 week of the intervention (in person or via phone depending on participant preference), and at follow-up (in person).
Beverage taste testing	Prior to randomization, child participants will taste pairs each study beverage (10 mL) in randomized order and rate which beverage they like better and which beverage tastes sweeter using the taste enclosed taste testing form. Participants will rinse with water between each test. Taste testing will be completed in a private room and supervised by trained RAs. Child participants will also complete taste testing at follow-up.
Compliance questionnaires	Participants (child and their parent) will complete an online, 4-item questionnaire daily throughout the intervention to assess compliance (percentage of assigned beverages consumed, assessment of whether caffeinated SSB were consumed in violation of the study protocol, and if so, the brand and quantity consumed).
Randomization and Blinding	Following baseline assessments, child participants will be randomized using sex-stratified permuted block randomization into one of three arms: 1) caffeine-free SSBs (caffeine-free Pepsi) 2) unsweetened sparkling water (LaCroix) or 3) control (Pepsi).

	Assigned beverages will replace usual caffeinated SSB consumption, as assessed at enrollment.
Beverage distribution	A two-week supply of beverages (corresponding to randomization and the amount of SSBs typically consumed) will be provided. If a participant runs out of beverages, the study team will provide additional beverages. Children will be counseled to drink only the study drinks provided or water and not to consume any other beverages during the two week intervention. Parents will also be counseled regarding encouraging their child to consume only the study beverages or water throughout the two week study period.
Compliance and reminders	Compliance will be assessed by collection of empty beverage containers. Empty containers will be picked up by the study team at the end of the intervention to minimize participant burden. If a participant is provided with additional beverages, empty containers will be requested prior to distribution of more beverages. Compliance will be further monitored during dietary recalls.
Mitigation of withdrawal symptoms	If a child experiences headaches, nausea, or other discomfort, they will be asked to report symptoms using the CWSQ before taking pain or anti-nausea remedies. Children and their parents will be discouraged from using over-the-counter medications, unless the severity of the symptoms are reported to be above a pre- determined threshold (rating of 4 or higher on the CWSQ Likert scale). In addition, participants will be strictly instructed not to use any pain remedy containing caffeine.

Data analysis:

Caffeine withdrawal scores will be collected using the 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.

Dietary recalls 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.

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, but instead instructed to replace their usual beverages with the study drinks or 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.

There are several potential limitations to our proposed study. The first is that successful recruitment and data collection with children presents unique challenges. However, we are recruiting from a large sample of children throughout the greater Washington metropolitan area and our team has extensive experience conducting research with children. Another challenge is that participants in the clinical study may consume caffeinated SSBs or other caffeine- and/or sugar-containing products, which would minimize the likelihood of observing withdrawal symptoms. We will account for this by assessing diet using 24-hour dietary recalls, as well as daily online compliance questionnaires. We also acknowledge that those who do not consume still/seltzer water may be opposed to consumption. However, we have successfully randomized seltzer water naïve participants to consume them previously. It is also possible that the opaque wrapper may be insufficient to maintain blinding of study beverage assignments. However, transferring commercially available carbonated beverages to a separate and unidentifiable container is not possible, as opening containers prior to consumption would result in lost carbonation and altered taste.

E. Study Population – (Gender and Minority Inclusions):

The subject population will be comprised of 60 children, both male and female, aged 8-11 (3rd to 5th grade) and their respective parent/legal guardian, for a total of 60 children and 60 parents. In addition to age range, inclusion criteria consists of reporting regular consumption of caffeinated sugar-sweetened beverages, defined in this study as consuming ≥ 12 ounces of caffeinated SSB's per day. Children under 8 years of age will be excluded to ensure that participants are able to adequately articulate their reasons for SSB consumption. Children who have a poorly managed chronic medical condition, a current or prior eating order diagnosis, or who report regular consumption (≥ 1 serving per week) of other caffeinated beverages, such as energy drinks, regular coffee, or hot tea will also be excluded to ensure that we are adequately able to evaluate study aims and outcomes.

We will enroll children whose parents speak Spanish, as long as the child speaks English. This is necessary because sugar-sweetened beverage consumption is particularly prevalent in Hispanic/Latino families. We will protect these subjects by having members of our research team who are fluent in Spanish communicate with them throughout the study to make sure that completely understand the study rationale and procedures and so that we can easily address any of their questions or concerns.

F. Human Subjects (Risks & Benefits)

All sources of research material will be obtained from the human subjects in this study for research purposes. Materials consist of self-reported data for the following items:

- Name
- Age
- Contact information (phone #, email) – *used only for contacting active participants to schedule study visits*
- Race/ethnicity
- Gender
- 24-hour dietary recalls
- Daily caffeine withdrawal symptoms questionnaires (CWSQs)
- Daily compliance surveys

Additionally, anthropometric measurements of height and weight will be taken on-site at the baseline and follow-up visits.

Recruitment Plan

The study will be advertised to parents of children 8-11 years old (3rd-5th grade) through on-site recruitment by Dr. Meni and a trained study research assistant (RA). Recruitment

will take place in-person at community sites and/or events, while ensuring minimal disturbance to site/event flow. If interested in participating, the RA will administer a brief eligibility checklist (enclosed), and if eligible, participants will be asked if they are interested in participating. Given the large volume of children served by the participating sites, we do not anticipate any problems recruiting and retaining a diverse sample of children. If the potential participant has questions that the research assistant (RA)/clinical study coordinator (CRC) cannot answer, the RA/CRC will immediately contact Dr. Meni on her cell phone to provide clarification. Recruitment techniques used will include flyers or other print media. Subjects will not be recruited through any use of records.

The study team will ensure that this study and all recruitment is conducted in full conformity with the Regulations for the Protection of Human Subjects of Research codified in 45 Part 46 of the Code of Federal Regulations.

Participant confidentiality is strictly held in trust by the participating investigators, their staff, the sponsor and their agents. This confidentiality is extended to cover information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

Informed Consent

At the screening visit, a study team member will explain the study to the parent and child. The study team member will first go over the consent form with the parent, prior to going over the assent form with the child.

Parents and children will be asked to read and review the consent and assent form, respectively. Both (the parent and the child) will have the opportunity to ask any questions before signing the respective form. Participant consent (parent) or assent (child) will then be documented by having participants sign the document. All parents and children will receive a verbal lay explanation of the purposes, procedures, and potential risks of the study and of their rights as research participants.

Children and their parent will be given the opportunity to discuss the study with their friends and family members and will be welcome to take the consent or assent form home prior to agreeing to participate. The parent will sign the informed consent document(s) and the child will sign the assent document prior to any study procedures. The parent may withdraw consent at any time throughout the course of the study. A copy of the informed consent document will be given to the parent for their records. A copy of the assent document will be given to the child.

G. Risks and Side Effects:

It is important to note that all research studies have some risk; however, risks associated with participation in this study are minimal. Potential risks are listed in the table below:

Risk/Side Effect	Probability
General: The child may find the time needed to complete this research study an inconvenience.	Rare
Confidentiality: It is possible that other participants and individuals external to the study may find out that a participant took part in the research, in which case, information derived may be conveyed to others external to the group.	Occasional
Questionnaires: Completing the beverage screener, CWSQ, and compliance questionnaires may be uncomfortable, burdensome, or embarrassing for some participants.	Occasional
Dietary Recalls: Completing dietary recalls may also be uncomfortable, burdensome, or embarrassing for some participants.	Rare
Beverage Taste Ratings: While performing the taste tests, some children may find the taste unpleasant.	Occasional
Study Intervention: Participants may experience withdrawal symptoms such as headaches, fatigue, changes in mood, difficulty concentrating, and gastrointestinal discomfort.	Common
Consumption of Assigned Study Beverages: Some participants may not like the taste of the beverages provided and may find consuming them for 2 weeks to be uncomfortable.	Occasional

This study is minimal risk since the procedures do not exceed the probability and magnitude of physical or psychological harm than those ordinarily encountered in daily life, or in routine medical, or psychological examinations. Because the risks associated with the study are minimal, the contribution of our study to understanding effects of caffeinated SSB restriction outweighs the risks. Thus, the risk-to-benefit ratio of the study is low. The study procedure and the potential risks associated are described below and will be disclosed in the study consent and assent forms.

Steps taken to minimize risk and to protect subjects' welfare:

General: The majority of procedures will be conducted remotely using the internet or telephone, which will reduce participant burden.

Dietary recalls: Data collected will be de-identified to ensure that responses are not directly linked to the subject's identity and are linked only through a code retained by the Principal Investigator.

Beverage Taste Ratings: We have minimized this risk by asking each subject to consume only a very small amount of each study beverage.

Study Intervention: Withdrawal symptoms will be closely monitored through the completion of daily caffeine withdrawal symptoms questionnaire. In the event that adverse side effects are observed, Dr. Meni will be contacted immediately and advise appropriate action.

Consumption of Study Beverages: All study beverages are commercially available beverages. Flavored unsweetened sparkling water will be provided to help with palatability

Confidentiality: We will minimize risks by de-identifying participant data and linking research data collected to the participant's name only through a code retained by the Principal Investigator.

H. Benefits:

There are no direct benefits to participation in this study. However, because the study aims to understand whether removal of caffeinated SSBs from the diet is feasible, this pilot study will inform the design of future interventions and policies for lowering SSB consumption in youth.

I. Outside Consultants/Collaborators

Not applicable.

J. Contractual Agreements

Not applicable.

K. Costs To Subjects:

The George Washington University will provide the study beverages to subjects for free. Subjects will not be charged for anything else we do that is part of the study and as such, there are no costs to participants.

L. Conflicts Of Interest:

Salary support for this study is provided by the National Institute of Health and the Milken Institute School of Public Health at the George Washington University. REDCap® support

is provided by The Clinical and Translational Science Institute (CTSI) at Children's National. All key study personnel will follow the Human Research Protections Program Investigator, Study Staff, and Family Member Conflicts of Interest (COI) Policy. The PI nor any of the study staff members have conflicts of interest to report.

M. Confidentiality:

All procedures will take place in a private room to ensure the participant's privacy. The study participant's contact information will be securely stored at the study site for internal use during the study. At the end of the study, all research records will be stored in a secure location for the time period dictated by the sponsor and institutional regulations. The research data will not include the participant's identifying information. Identifiers including name, phone number, and email address will be collected for the clinical pilot study; however, all data will be de-identified and identifiers will not be disclosed. The study data entry and study management systems used by research staff will be secured and password protected. Confidentiality of all study information will be maintained by assigning participants code numbers, which will be used for entering and storing data electronically. Data that have been collected as a part of this study will be retained in secure, password-protected electronic files until 6 years after enrollment of the last participant.

Participant confidentiality is strictly held in trust by the participating investigators, their staff, the sponsor and their agents. This confidentiality is extended to cover information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

Data Storage

All data will be entered and managed using RedCap, a password-protected data management system. Data will be entered by trained research assistants and Dr. Meni will check RedCap weekly during periods of active data collection to ensure that data entry is correct and up to date. Dr. Meni will keep all study records in a locked cabinet for 6 years after enrollment of the last participant.

Data Analysis

Data analysis will take place on-site at The George Washington University. Data security will be maintained by precluding personal or identifying data from analysis. Additionally, data analysis will take place on password-protected computers and access to data will be restricted to participating investigators, their staff, the sponsor and their agents. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

Destroying Data/Study Materials

Six years following enrollment of the last study participant, electronic data files will be deleted. Paper files will be shredded.

Protecting the Welfare of Vulnerable Participants

The privilege of confidentiality does not extend to information about sexual or physical abuse of a child. If any member of the research team has or is given such information, he or she is required to report it to the appropriate authority or agency, such as child protective services, a law enforcement agency, or your State's toll-free child abuse reporting hotline. The obligation to report includes past and current alleged or reasonably suspected abuse as well as past or current known abuse. Examples of such abuse include physically harming your child or having inappropriate sexual contact with your child.

N. Subject Compensation:

Pilot study participants will receive compensation of up to $175, including $75 for the baseline visit involving consent/assent, questionnaire completion, taste testing, dietary recall, $25 for the mid-point visit after Week 1, and $75 for the follow-up visit including questionnaire completion, taste testing, dietary recall, and qualitative in-depth interview. Participants who withdraw from the study will be appropriately compensated for the study activities that they did complete. In addition, participants will be provided with additional compensation to cover the cost of travel to/parking at the GWSPH.

O. Facilities and Equipment

There is no major equipment required for this project. The primary facilities that will be used are the following:

Food and Nutrition Assessment Core (FNAC): The FNAC is located within the Milken Institute School of Public Health and provides state-of-the-art methods for dietary data collection from research participants. FNAC services include: 1) collection of dietary recall (in person or by telephone) data using the Nutrient Data System for Research (NDSR); 2) nutrient analysis of food records, food frequency questionnaires, menus, and recipes; and 3) consultation on appropriate data collection approaches for nutrition components of research studies. The FNAC interviewing room is approximately 400 sq. feet and includes 2 interviewer cubicles, each with a high-speed computer, monitor, keyboard, phone, head-set, and desk space. Resource support equipment includes a copy machine, printers, a fax machine, and other standard office equipment. This will allow us to conduct dietary recalls in person throughout the study and to rigorously analyze the data.

Psychology of Exercise and Nutrition Sciences Lab: There is space in the GWSPH building for behavioral studies. This lab space is dedicated for research use and includes three desks and two PC computers equipped to perform word processing, as well as statistical analyses using SPSS/PAWS software. This lab also includes ample space for storage of various research resources including adequate filing cabinets for the use of securing and storing hard data. These computers will be critical for facilitating efficient

data entry and regular follow-up with participants via online questionnaires and text message reminders.

P. References & Literature Cited

1. Hu FB. Resolved: there is sufficient scientific evidence that decreasing sugar-sweetened beverage consumption will reduce the prevalence of obesity and obesity-related diseases. *Obes Rev.* 2013;14(8):606-619.
2. Knight CA, Knight I, Mitchell DC, Zepp JE. Beverage caffeine intake in US consumers and subpopulations of interest: estimates from the Share of Intake Panel survey. *Food Chem Toxicol.* 2004;42(12):1923-1930.
3. Juliano LM, Griffiths RR. A critical review of caffeine withdrawal: empirical validation of symptoms and signs, incidence, severity, and associated features. *Psychopharmacology (Berl).* 2004;176(1):1-29.
4. Avena NM, Rada P, Hoebel BG. Evidence for sugar addiction: behavioral and neurochemical effects of intermittent, excessive sugar intake. *Neurosci Biobehav Rev.* 2008;32(1):20-39.
5. Welsh JA, Lundeen EA, Stein AD. The sugar-sweetened beverage wars: public health and the role of the beverage industry. *Curr Opin Endocrinol Diabetes Obes.* 2013;20(5):401-406.
6. Vargas-Garcia EJ, El Evans C, Cade JE. Impact of interventions to reduce sugar-sweetened beverage intake in children and adults: a protocol for a systematic review and meta-analysis. *Syst Rev.* 2015;4:17.
7. Malik VS, Popkin BM, Bray GA, Despres JP, Hu FB. Sugar-sweetened beverages, obesity, type 2 diabetes mellitus, and cardiovascular disease risk. *Circulation.* 2010;121(11):1356-1364.

Q. Appendix

Caffeine Withdrawal Questionnaire

Below is a list of feelings/experiences people have. Circle the number that best describes how you are feeling/what you are experiencing **RIGHT NOW**.

	Not at all	A little	Moderately	Quite a bit	Extremely
1. Low energy	0	1	2	3	4
2. Yawning	0	1	2	3	4
3. Alert	0	1	2	3	4
4. Tired	0	1	2	3	4
5. Happy	0	1	2	3	4
6. Trouble Concentrating	0	1	2	3	4
7. Nervous/Jittery	0	1	2	3	4
8. Heavy feelings in arms and legs	0	1	2	3	4
9. Sad	0	1	2	3	4
10. Grumpy	0	1	2	3	4
11. Urge to do homework	0	1	2	3	4
12. Sick/Flu-like	0	1	2	3	4
13. Headache	0	1	2	3	4
14. Talkative	0	1	2	3	4
15. Sluggish or slowed down	0	1	2	3	4
16. Upset stomach/stomachache	0	1	2	3	4
17. Focused	0	1	2	3	4
18. Desire to socialize	0	1	2	3	4
19. Energetic	0	1	2	3	4
20. Nausea/vomiting	0	1	2	3	4
21. Muscle pain/stiffness/aches	0	1	2	3	4
22. Discouraged	0	1	2	3	4
23. Have to urinate too much	0	1	2	3	4

Demographic Questionnaire

Instructions: Please circle one answer in response to each question below. Please answer with regard to the child who is participating.

1. **What is your child's sex?**

   a. Male
   b. Female

2. **How old is your child?** _____ years

3. **What is your child's race?**

   a. White/Caucasian
   b. Black/African American
   c. Asian
   d. Mixed race
   e. Other, please specify _____
   f. Prefer not to answer

4. **Is your child Hispanic?**

   a. Yes
   b. No

5. **Is your child eligible for free or reduced-price lunch?**

   a. Yes
   b. No

6. **Were you born in the United States?**

   a. Yes
   b. No

      If no, where were you born? _____

      When did you move to the United States? _____

7. **Was your child born in the United States?**

   a. Yes
   b. No

      If no, where was your child born? _____

      When did you move to the United States? _____

Compliance Questionnaire

1. **Did you drink the assigned study beverages {insert specific type for participant per randomization} today? If so, how many?**

Please circle: YES or NO

Quantity: _____ cans OR _____ ounces

Brand and name of beverage:

2. **Did you drink any other sugar beverages today? If so, which ones and how many/how much?**

Please circle: YES or NO

Quantity: _____ cans OR _____ ounces

Brand and name of beverage:

3. **Did you drink juice today? If so, what kind and how much?**

Please circle: YES or NO

Quantity: _____ cans OR _____ ounces

Brand and name of beverage:

4. **Did you have any caffeinated beverages, such as coffee, tea, or hot chocolate today? If so, which ones and how many/how much?**

Please circle: YES or NO

Quantity: _____ cans OR _____ ounces

Brand and name of beverage:

Beverage Questionnaire

Name: _____ Date: _____

Instructions

In the past month, please indicate your response for each beverage type by marking an "X" in the square for "how often" and "how much each time".

1. Indicate how often you drank the following beverages, for example, if you drank 5 glasses of water per week, mark 4-6 times per week.
2. Indicate the approximate amount of beverage you drank each time, for example, if you drank 1 cup of water each time, mark 1 cup under "how much each time".
3. Do not count beverages used in cooking or other preparations, such as milk in cereal.
4. Count milk added to tea and coffee in the tea/coffee with cream beverage category NOT in the milk categories

	HOW OFTEN (MARK ONE)							HOW MUCH EACH TIME (MARK ONE)				
Type of Beverage/Drink	Never or less than 1 time per week (go to next drink)	1 time per week	2-3 times per week	4-6 times per week	1 time per day	2+ times per day	3+ times per day	Less than 6 fl oz (3/4 cup)	8 fl oz (1 cup)	12 fl oz (1 1/2 Cups or 1 soda can)	16 fl oz (2 cups or 1 soda bottle)	More than 20 fl oz (2 1/2 cups)
Water (plain/unsweetened, water or seltzer)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
100% Fruit Juice	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sweetened Juice Drinks (e.g. fruit drinks such as KoolAid, lemonade, punch, Sunny Delight)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Diet Fruit Drinks (e.g. light lemonade, light juice drinks)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Whole Milk	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Reduced Fat Milk (2%)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Low Fat/Fat Free Milk (Skim, 1%, Buttermilk, Soymilk)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Regular, caffeinated, Soft Drinks/ Regular Soda with caffeine (e.g. Coke, Pepsi, Mountain Dew)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Caffeine-free Regular Soft Drinks/Soda (e.g. Sprite, Fanta, Caffeine-free Coke)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Diet/Artificially Sweetened Soft Drinks including diet soda, (e.g. Diet Coke, Diet Pepsi, Coke Zero)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Caffeine-free Artificially Sweetened Soft Drinks/Soda (e.g Caffeine-free Diet Pepsi, Diet Sierra Mist, Sprite Zero)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sweet Tea (e.g. Arizona Iced Tea, Nestea, Pure Leaf)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Diet Iced Tea (e.g. Diet Snapple, Diet Nestea)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Hot Tea or Coffee, with cream and/or sugar	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Hot Tea or Coffee, black, without artificial sweetener (no cream or sugar)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Hot Tea or Coffee, black, with artificial sweetener (e.g. Splenda, Equal, Sweet N' Low)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Energy Drinks (e.g. Red Bull, Rockstar, Monster, etc.)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Diet/Artificially Sweetened Energy Drinks (e.g. sugar-free RedBull, Monster Zero)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sports Drinks (e.g. Gatorade, Powerade, etc.)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Diet/Artificially Sweetened Sports Drinks (e.g. Powerade Zero, G2)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Beverage Taste Testing Form

Instructions for Pediatric Subjects. Show the cups to the subject and say: "We're going to play a game with things to taste. Here are two cups. You will taste what's inside the first cup, swish it around your mouth (BUT don't swallow) and I will tell you when to spit it out in the big cup. You will then rinse your mouth with water and then taste what's inside the second cup. I will tell you when to spit it out. Then I want you to POINT TO which one you like better - the first one or the second one. You will then rinse your mouth 2 times with water and we will do this again."

Notes:

- Be sure to underline which concentration is in position 1 for each pair.
- Use stopwatch to time solution in mouth for 5 seconds, and 1 minute between pairs
- Circle the

	Which one do you like better?				**Which one is sweeter?**				Notes
	A	B	C	D	A	B	C	D	
1.									
2.									
3.									
4.									
5.									
6.									

Qualitative Interview/Debrief Questions

a) How difficult was it for your child to drink only the study drinks?

b) Were other sodas/sugar-sweetened beverages available in the house during the intervention?

c) Did your child drink these other beverages? How much do you think?

d) How much oversight do you have over their beverage intake? Do you think they got other beverages elsewhere? Did they sneak soda/sugar-sweetened beverages?

e) Did your consumption change at all as a result of participating in this study? How so?

f) What was the hardest part of participating in this study?

g) What was the best part of participating in this study?

h) Anything else that you can tell us about your experience in this study?

Reminder Messages

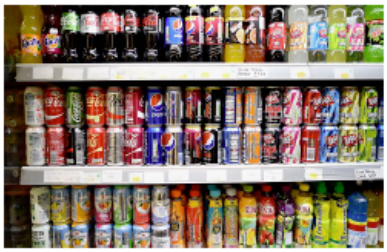
The following reminders will be sent to parents during the intervention:

"Hi ___[insert parent name]__. This is a friendly reminder to please complete the study questionnaires."

"Hi ___[insert parent name]__. This is a friendly reminder to please remind ___[insert child name]_ to drink only the study drinks provided until ___[insert date of follow-up visit]___.

DOES YOUR CHILD LIKE SODA OR SWEET TEA?

RECRUITING CHILDREN 8-11 YEARS OLD



Please consider participating in our study!

$175 Compensation

- **What does participating involve?**
  The study involves asking your child to drink sugar-free and/or caffeine free soft drinks for two weeks. We will ask your child to complete daily questionnaires and participate in telephone interviews about their diet for three weeks.

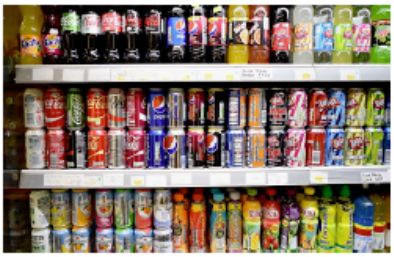
- **Is my child eligible?**
  Your child may be eligible if they are 8-11 years old and drink at least 12 ounces of sugar sweetened caffeinated beverages per day.

For more information, contact The George Washington University study team at: sugarstudy@gwu.edu.

IRB NUMBER: NCR191271
IRB APPROVAL DATE: 06/07/2019

¿LES GUSTAN A SUS HIJOS SODA O TÉ DULCE?

Reclutando a Niños 8-11 años



Por favor, considere participar en nuestro estudio.

$175 de Reembolso

- **¿Que implica participar?**
  El estudio implica pedir a su hijo tomar bebidas sin azúcar y/o cafeína por dos semanas. Pediremos que su hijo complete cuestionarios diarios y participe en entrevistas telefónicas sobre su dieta por tres semanas.

- **¿Es eligible mi hijo?**
  Su hijo pueda ser elegible si tiene 8-11 años y si tome por lo menos 12 onzas de bebidas azucaradas con cafeína cada día

Para más información, por favor, contactor el equipo de estudio del George Washington University a: sugarstudy@gwu.edu

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