



Feasibility and acceptability of a randomized controlled trial to investigate withdrawal symptoms in response to caffeinated sugary drink cessation among children

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ABSTRACT

Background: Sugary drinks (SDs) are key contributors to excess added sugar intake and the predominant source of caffeine among children. Chronic caffeine intake causes dependence, and evidence for sugar dependence is emerging. Development of withdrawal symptoms may pose an obstacle to SD cessation among children. We examined the feasibility and acceptability of a three-arm randomized controlled trial (RCT) designed to investigate withdrawal symptoms resulting from replacement of children's usual caffeinated SD intake with either caffeine-free alternatives or caffeine-free and sugar-free alternatives, compared with continued consumption of caffeinated SDs.

Methods: Twenty-nine children 8–12 years old, who consumed ≥ 12 ounces caffeinated SDs daily, enrolled. The two-week RCT required three in-person meetings and daily completion of electronic questionnaires to assess withdrawal symptoms and intervention adherence. Children were randomized to replace their usual caffeinated SD consumption with 1) caffeine-free alternatives, 2) caffeine-free and sugar-free alternatives, or 3) caffeinated SDs (control), provided by the study team. Feasibility and acceptability were assessed quantitatively and qualitatively.

Results: Twenty-eight participants (97%) completed the study. Adherence was high, with 73% reporting compliance with beverage assignments, and 76% completing all questionnaires. In qualitative interviews at follow-up, children described feelings of importance and commitment, and parents did not find the procedures to be overly burdensome. While challenges to adherence were reported (e.g., child wanting other SDs, time commitment), participants described innovative strategies (e.g., designating a place for study drinks in the refrigerator) to maintain adherence.

Conclusion: Results indicated high levels of RCT feasibility and acceptability. The reported barriers and strategies for adherence will inform modifications required to design a larger and longer-term trial investigating withdrawal symptoms after SD cessation in children.

1. Introduction

Excess sugary drink (SD) intake contributes to obesity and chronic disease [1]. SD consumption among children exceeds recommendations [2] and reducing SD intake is challenging [3]. Over 60% of children in

the United States (U.S.) consume SDs daily [4], and consumption is highest among children from minority and low-income backgrounds [5]. Along with their high sugar content, SDs are also the primary source of caffeine among children [6]. Added caffeine in already highly palatable SDs increases their hedonic and reinforcing properties [7,8]

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and may further promote excess added sugar intake, a well-established risk factor for obesity and cardiometabolic disease [1].

Repeated caffeine intake causes dependence (i.e., tolerance and withdrawal) in adults [9], and compelling evidence for sugar dependence is emerging [10,11]. In accordance with addiction theory, withdrawal following discontinuation of a highly rewarding substance can trigger withdrawal symptoms, which motivate reinstatement of use [12]. Withdrawal may therefore represent a significant obstacle to SD reduction among children, and may develop as a result of either separate or combined effects of sugar and/or caffeine removal. In the substance use literature, acute withdrawal intensity in the first 48–72 h is associated with increased risk of substance reinstatement, even after symptoms subside [13]. Thus, development of withdrawal symptoms during short-term SD cessation may predict challenges to long-term adherence to public health guidance to lower SD intake.

In our prior work with families from predominantly low-income and minority backgrounds [14], parents reported that their child developed physical, affective, and cognitive symptoms (e.g., headaches, irritability, poor concentration) when SDs were restricted. Furthermore, children eight to 14 years of age described a perceived need for SDs and reported physical, cognitive, interpersonal, and emotional benefits of SD consumption [15]. Withdrawal symptoms upon cessation of highly processed foods in children have also been documented [16]. Only one prior study [17], of a three-day duration and single-arm design (i.e., no control group), has examined withdrawal symptoms in response to SD cessation. In this study, adolescents were enrolled regardless of whether they consumed caffeinated or caffeine-free SDs, which precluded assessment of whether the withdrawal symptoms observed were due to separate or combined effects of sugar and/or caffeine removal [17].

Herein, we report the feasibility and acceptability of an innovative, three-arm randomized controlled trial (RCT), in which children 8–12 years old who reported daily consumption of caffeinated SDs, were randomly assigned to either replace their usual caffeinated SDs with caffeine-free SDs or caffeine-free, unsweetened sparkling water for two weeks, or to continue caffeinated SD intake.

2. Methods

2.1. Study design

The three-arm RCT was designed to measure the separate and combined effects of sugar and/or caffeine removal on development of withdrawal symptoms over two weeks. Children were randomly assigned to replace their usual caffeinated SD intake with either caffeine-free (e.g., caffeine-free Pepsi™) beverages, unsweetened sparkling water (LaCroix™), or control (caffeinated SDs) for two weeks. The target sample size was 60 children. However, the study was unfortunately stopped in March 2020 due to the COVID-19 pandemic, at which point, 29 children had been enrolled.

2.2. Recruitment and enrollment

Children were recruited from schools, community organizations, and community events primarily serving low-income, minority families throughout the greater Washington, District of Columbia metropolitan area and via study advertisements on neighborhood listservs and in a local newspaper. Recruitment and enrollment took place from June 2019 through March 2020, prior to halting indefinitely due to the COVID-19 pandemic. Inclusion criteria were parent or guardian (hereafter parent) reporting that their child: 1) was between 8 and 12 years; 2) consumed ≥ 12 ounces of caffeinated sugary, non-diet, drinks (e.g., Coca-Cola™, Pepsi™, Mountain Dew™, Arizona Iced Tea™) per day; and 3) spoke English fluently. Parents were not required to speak English, as study recruitment and consent materials were translated into Spanish by two, part-time, bilingual research assistants (RAs). Children were excluded if parents reported that their child: consumed regular or

caffeine-containing coffee, hot tea, or energy drinks (e.g., Red Bull™, Monster™) ≥ 1 time per week, had been diagnosed with diabetes, had asthma requiring medication, had a current or prior eating disorder diagnosis, had a history of migraines, or took medication(s) which could impact withdrawal symptoms. Frequent energy drink, caffeinated hot tea, and/or regular coffee consumption was a criterion for exclusion because these beverages contain more caffeine than sodas and sweet teas [18] and have highly variable sugar and caffeine content. It was also not possible to acquire caffeine-free and/or sugar-free replacements for energy drinks, caffeinated hot tea, and regular coffee in a blinded manner because canned or bottled caffeine-free and/or sugar-free versions of these beverages are not commercially-available. Eligibility was assessed by a trained study team member during a brief phone screening. The study protocol was reviewed and approved by the Institutional Review Board at The George Washington University (GW). The participants' parent(s) provided written informed consent, and the participants provided written assent, prior to beginning the study procedures.

2.3. Data management and randomization

Study data were collected and managed using REDCap™ electronic data capture tools hosted at Children's National Hospital. Sex- and race-stratified permuted block randomization was performed by a statistician and the randomization sequence was concealed from the investigators and RAs conducting the study procedures.

2.4. Study procedures

All study visits (baseline, mid-intervention, and post-intervention) took place in the Exercise and Nutrition Sciences (EXNS) Laboratory at the Milken Institute School of Public Health (GWSPH) at GW. At baseline, the parent completed a brief demographic questionnaire, and the child's height and weight were measured by a trained RA, in duplicate, using standard methods [19]. The child's usual beverage consumption was assessed using an adapted version of the beverage intake questionnaire (BEVQ-15) [20], which is validated in children [21]. The BEVQ-15 was administered by the RA and completed by the child, with assistance from their parent. To assess the presence of withdrawal symptoms, the child completed a child-adapted version of the validated Caffeine Withdrawal Symptoms Questionnaire (CWSQ) [22], administered by the RA. Following completion of CWSQ, the child completed a brief taste test. Taste tests were conducted primarily to determine the extent to which children liked the study beverages, which was likely to impact adherence to randomized beverage assignments. Taste testing involved each child tasting 10 mL of each of the three study beverages and a fourth beverage (diet soda) in a randomized, blinded, and paired fashion. Six paired trials were performed, 1 min apart, to ensure that all beverages were tasted in comparison with each other. For each pair, the child was instructed to taste the first beverage for 5 s and then expectorate and rinse with water before tasting the second beverage. After tasting both beverages, the child was asked to indicate which beverage they liked better and which was sweeter. Participants then completed a 24-h dietary recall administered by a RA, with assistance from their parent.

2.5. Two-week intervention

Children were randomized to consume either 1) caffeine-free SDs (caffeine-free, sugar-sweetened Pepsi™), 2) caffeine-free and sugar-free beverages (unsweetened sparkling water (LaCroix™)), or 3) caffeinated SDs (control; caffeinated, sugar-sweetened, regular Pepsi™). Each child was provided with a two-week supply of study beverages, based on their reported usual SD intake, per randomization. For example, if a child reported habitual consumption of 12 ounces of SDs twice daily, they were provided with two cans of study beverages per day, for a total of 28

cans over the two-week study period. All participants were instructed to consume the study beverages in quantities and at frequencies reflecting their usual SD intake, and were given a study reminder sheet to take home. The reminder sheet reinforced the key study instructions, including: 1) to drink only the study drinks provided and plain water ad libitum; 2) to drink the study drinks whenever they would normally have a sweet drink, including 100% fruit juice; 3) to drink as much plain water as they liked; 4) to complete the surveys emailed each day; 5) to keep the empty cans and store them in the bags provided; 6) it was not necessary to finish the study drinks; and, 7) to not share the study drinks with family or friends.

Blinding of study beverage assignments (to the extent possible, given that sparkling water has a distinctly different taste compared with caffeinated or caffeine-free cola) was ensured by covering beverage cans in an opaque wrapper, which prevented participants from viewing the label. Aside from the assigned study beverages, participants were instructed to avoid other sugary (e.g., lemonade, juice), caffeinated (e.g., coffee), or sugary and caffeinated (e.g., Mountain Dew™, energy drinks) beverages, to minimize interference with the intended removal of sugar and/or caffeine.

Each day throughout the two-week intervention, parents received an e-mail at 4:00 p.m. with a link to a brief, online, 4-item beverage adherence questionnaire (via REDCap™) and an electronic version of the CWSQ. The beverage adherence questionnaire was developed by the study team and included one item to assess the percentage of assigned beverages (per randomization) consumed and three items to assess if any sugary and/or caffeinated beverages (other than assigned study beverages) were consumed in violation of the study protocol, and if so, the brand and quantity consumed. If the daily survey was not completed by 8:00 p.m. each day of the intervention, the study team sent a text message reminder to the parent to encourage survey completion.

2.6. Follow-up assessments

One week after randomization at the baseline visit, participants and their parent returned for a brief, mid-intervention visit. During this visit, the child completed the CWSQ, a second, interviewer-administered 24-h dietary recall with parent assistance, and the daily 4-item beverage adherence questionnaire. The intervention instructions were reiterated by the RA, and if necessary, participants were provided with additional study beverages, per their randomization.

Two weeks after randomization, the child and their parent returned a final time for the post-intervention, follow-up visit. All baseline assessments, except for the demographic questionnaire and BEVQ-15 were repeated, and a qualitative interview with the child and parent was conducted by the Principal Investigator (ACS), using a semi-structured interview guide designed by several members of the research team (ACS, AJV, JS). The guide contained open-ended questions about parent and child satisfaction with the study and about aspects of the intervention that were most enjoyable, most disliked, and/or most challenging. Qualitative interviews were recorded and typically lasted approximately 15 min. Participants who completed all three study visits were provided with \$175 as compensation (distributed in increments following each study visit) in the form of gift cards, and received additional compensation for the costs of transportation and/or parking.

2.7. Data analysis

The primary aim was to determine the feasibility and acceptability of the RCT. Descriptive statistics, including means and frequencies, were used to summarize participant characteristics and rates of study recruitment, enrollment, completion, and attrition. Rates of questionnaire completion, and participant adherence to the beverage assignments and study procedures were also used to examine feasibility, and were compared across treatment groups using chi-square tests. P-values <0.05 were considered statistically significant.

Acceptability was assessed using data collected during the brief qualitative interview conducted with the child and parent at the post-intervention study visit (described above). All interview audio recordings were manually transcribed verbatim by trained RAs and subsequently checked by a second research team member. One research team member (KC) coded the post-intervention interview transcripts using an inductive approach informed by grounded theory [23]. The NVivo Pro software package (version 12; QSR International, Inc.; Burlington, MA, USA) was used to code the transcripts, and a codebook containing codes reflective of the participants' words and sentiments was created. Codes were modified and refined iteratively and new codes were added as they emerged. Previously coded transcripts were reviewed to ensure that all content was coded using the final codebook. Transcripts and the final codebook were reviewed by a second research team member (SH) and any discrepancies were discussed until consensus was reached or the disagreement was resolved by a third team member (ACS), as necessary. Two research team members (KC and SH) then independently identified themes and subthemes, which were discussed with two additional team members (ACS and EFB). Themes and subthemes were further organized and refined, and quotations from participants and their parents were selected relevant to each theme and subtheme.

3. Results

As shown in Fig. 1, over 1,300 parents were directly or indirectly approached regarding the possibility of their child's study participation through several distinct recruitment channels, including: 1) their child receiving a permission form (approximately $n = 1000$) regarding participation in a separate, related, SD study at their child's school, to which parents had the option to respond with their interest in being contacted about the RCT; 2) being directly approached by a study team member at community events including back-to-school nights (approximately $n = 100$), family-focused events hosted by community partners (approximately $n = 100$), and/or sports games hosted by a partnering afterschool program (approximately $n = 100$); and 3) via study advertisements posted at community centers and libraries and/or circulated via newspapers or neighborhood listservs throughout Washington D.C. (number of parents reached is unknown).

Parents of 177 children ($n = 115$ recruited via permission slips at school, $n = 50$ recruited from community events, and $n = 12$ recruited from study advertisements) indicated initial interest in their child's study participation. Fifty-six of these children were determined as potentially eligible based on the child meeting the inclusion criteria for the separate, related study at school and/or via an initial conversation with the parent at community events. For example, if a parent indicated interest in future contact on the permission form for the study taking place at school (which had similar inclusion criteria), but their child was not eligible for the study at school, then they were not contacted regarding participation in the RCT. Similarly, if a parent provided their contact info on a sign-up sheet at a community event, but their child was determined ineligible in a subsequent conversation while at the event, the parent was not contacted.

The study team was able to reach 49 of the 56 parents (88%) to assess their child's eligibility and confirm interest during a brief phone screening. Forty of the 49 volunteers screened were eligible for the RCT (82%). Of the nine who were ineligible, eight (89%) were ineligible due to reported beverage consumption (i.e., did not consume caffeinated SDs daily or regularly consumed coffee or energy drinks) and 1 (11%) was ineligible because of medical history (i.e., history of migraines). Of the 40 children that were eligible, 37 (93%) agreed to participate and 29 (73%) enrolled in the study (Fig. 1).

Characteristics of the 29 participants are summarized in Table 1. The sample was 66% African-American, 34% Hispanic, and 100% low-income based on parent-reported eligibility for free or reduced-price lunch. Usual SD intake was high, with participants reporting an

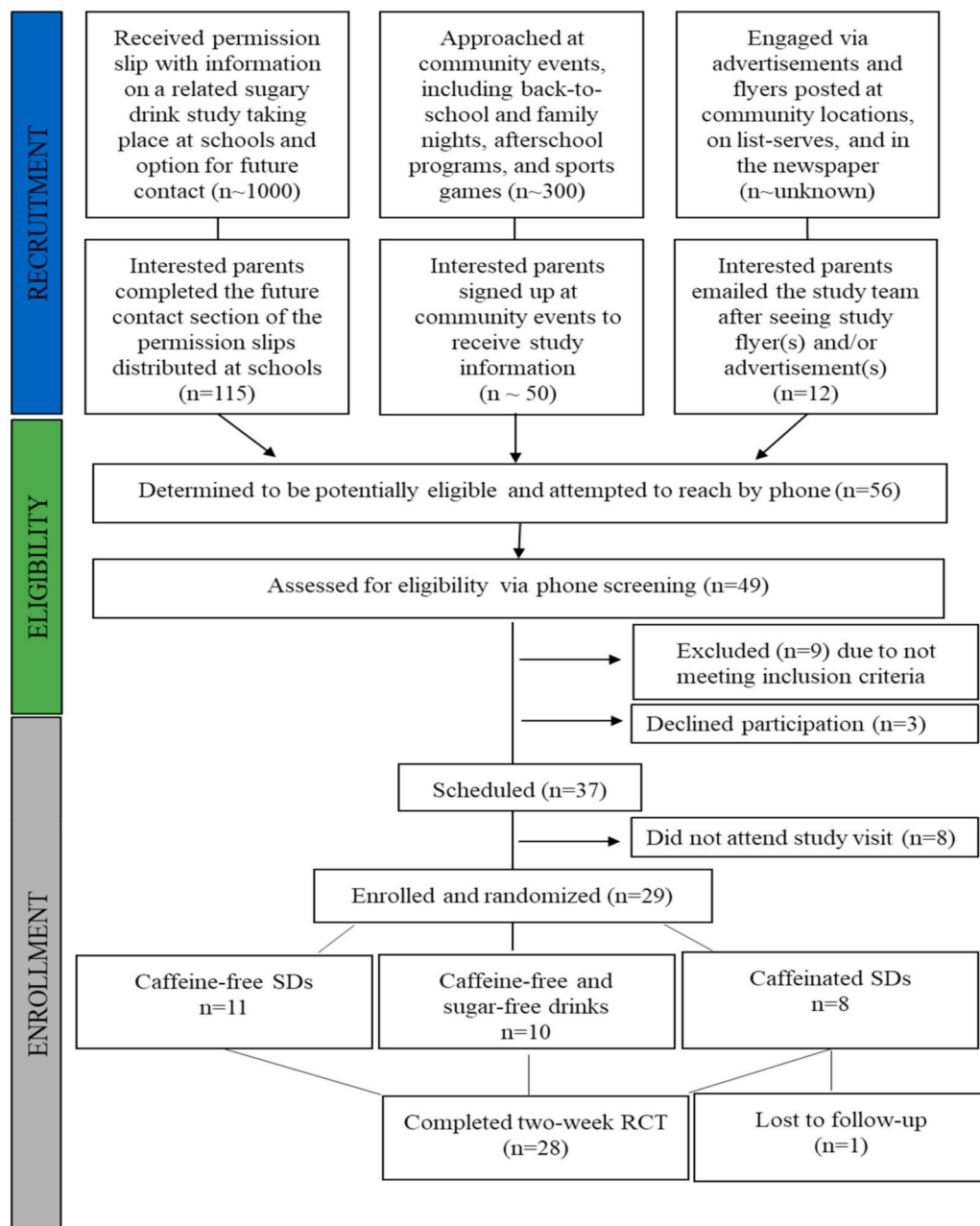


Fig. 1. Participant recruitment, eligibility assessment, enrollment, and completion.

Over 1,300 parents were directly or indirectly approached regarding the possibility of their child's study participation through several distinct recruitment channels. Parents of 177 children indicated initial interest in their child's study participation, of whom 56 were determined as potentially eligible and subsequently contacted for phone screening. Twenty-nine children ultimately enrolled in the study, of whom, 11 were randomized to caffeine-free SDs, 10 were randomized to caffeine-free and sugar-free drinks, and 8 were randomized to caffeinated SDs (control). 28 children completed the two-week trial.

average intake of 35.4 ± 4.9 ounces of SDs per day, approximately half of which (16.5 ± 2.3 ounces) was comprised of caffeinated SDs. During taste tests conducted at the time of enrollment, the majority of children reported a preference for caffeinated (79%) and caffeine-free (86%) SDs compared with sparkling water, while reported preferences for caffeinated SDs compared with caffeine-free SDs were mixed (57% reported a preference for caffeinated, while 43% reported a preference for caffeine-free; data not shown).

Completion of the daily questionnaire was feasible, with no statistically significant differences by treatment group (Table 2). Twenty-seven (93%) of the 29 participants completed 75% of the surveys and 22 (76%) completed all of the daily surveys. Twenty-one participants (72%) completed at least 75% of the surveys on time, defined as completing both the CWSQ and beverage log by 12 p.m. the following day after receiving them via email at 4 p.m. each day. Twelve participants (41%) completed all of the daily surveys on time. Twenty-six participants (90%) completed all surveys distributed during the first

72 h (3 days) after beginning the intervention, consistent with the time period of peak withdrawal reported for other substances.

Although not statistically significant likely due to small sample size, adherence to beverage assignments was highest among those randomized to consume caffeinated SDs (control group), compared with those randomized to the caffeine-free or caffeine-free and sugar-free (sparkling water) groups. Overall, 73% of participants (across all three groups) reported consumption of the study beverages and avoidance of SDs other than the study beverages at least 75% of the time throughout the intervention period (11 days or more of the 14-day intervention). During the first three days after randomization (reflecting the expected time period of peak withdrawal), 93%, 97%, and 86% of participants reported adherence to beverage instructions on days 1, 2, and 3, respectively (excluding participants with a missing survey on day 1, 2, or 3), with the highest rates of adherence observed among those randomized to consume caffeinated SDs (control). No evidence of tampering with the opaque wrappers was observed upon return of empty cans at

Table 1
Characteristics of participants at baseline (n = 29).

	N	%
Age		
8 years old	11	37.9
9 years old	5	17.2
10 years old	6	20.7
11 years old	6	20.7
12 years old	1	3.5
Age, years (mean ± SD)	9.3 ± 1.3	
Sex		
Male	17	59
Female	12	41
Race/ethnicity		
African-American	19	66
Hispanic	10	34
Free- or reduced- price lunch eligible^a	28	100
Parent born outside of the United States	7	24
Weight status^b		
Healthy weight	11	37.9
Overweight	6	20.7
Obesity	12	41.4
Sugary drink intake^c, oz. per day (mean ± SD)	35.4 ± 4.9	
Caffeinated soda and sweet tea, oz. per day (mean ± SD)	16.5 ± 2.3	

^a One participant missing data for free- or reduced-price lunch eligibility.

^b Based on BMI percentile, calculated using age and sex specific cut-offs.

^c Includes regular, non-diet soda (including both caffeinated soda and caffeine-free soda), sweet tea, fruit drinks, sports drinks, and 100% fruit juice.

the mid-intervention and post-intervention visits.

The study had high retention, indicating acceptability. Twenty-eight of the 29 participants completed the two-week study (97%) and 27 (93%) attended all three study visits. The one participant who did not complete the study had been randomized to the control (caffeinated SD) group. Parent and child responses during qualitative interviews at the post-intervention visit also provided evidence of intervention acceptability (Table 3), which was reported by participants across all three treatment groups. A key theme that emerged from the qualitative interviews was that children enjoyed the experience of study participation (n = 15), both with regard to attending the study visits (e.g., enjoying the taste tests) and more generally, the experience of participating in a study. For example, parents reported that their child enjoyed talking about the study with their friends and “felt important” being in the study. Parents also described that their child enjoyed challenging themselves and holding themselves accountable for adhering to the study procedures.

Parents felt that completing the daily questionnaire was manageable

Table 2
Adherence to daily questionnaire completion and consumption of assigned study beverages, overall and by treatment group.¹

	All (n = 29)	Caffeine-free (n = 11)	Caffeine-free and sugar-free (n = 10)	Caffeinated SD (control) (n = 8)
Questionnaire Completion, n (%)				
≥75% of surveys completed	27 (93%)	10 (91%)	10 (100%)	7 (88%)
100% of surveys completed	22 (76%)	8 (73%)	9 (90%)	5 (63%)
≥75% of surveys on time	21 (72%)	7 (64%)	8 (80%)	6 (75%)
100% of surveys on time	12 (41%)	2 (18%)	5 (50%)	5 (63%)
100% surveys in first 72 h	26 (90%)	11 (100%)	9 (90%)	6 (75%)
Reported adherence to beverage assignments, n (%)				
Adherent ≥ 75% of the time ²	19 (73%)	6 (67%)	6 (60%)	7 (100%)
Adherent on Day 1 ³	25 (93%)	9 (82%)	9 (100%)	7 (100%)
Adherent on Day 2	28 (97%)	11 (100%)	9 (90%)	8 (100%)
Adherent on Day 3 ⁴	24 (86%)	9 (82%)	8 (80%)	7 (100%)

¹No statistically significant differences by treatment group, likely due to small sample size.

²Three participants (n = 2 in caffeine-free group and n = 1 in the control group) did not complete at least 75% of the surveys and are therefore considered missing and not included in the denominator.

³Two participants (n = 1 in the caffeine-free and sugar-free group and n = 1 in the control group) did not complete a survey on Day 1 and are therefore considered missing and not included in the denominator.

⁴One participant, in the control group, did not complete a survey on Day 3 and is therefore considered missing and not included in the denominator.

(n = 10), and one child indicated that it provided the opportunity to spend time with their parent, separate from their siblings or family members. Children and/or their parents frequently described learning from study participation (n = 10), specifically gaining insight into their child’s diet during the 24-h recalls, and recognizing how many SDs their child typically consumed each day.

Although some children described enjoying the taste of the study beverage (n = 10, including n = 7, n = 1, and n = 2 in the caffeine-free, caffeine-free and sugar-free (sparkling water), and caffeinated SD (control) groups, respectively) or gradually beginning to accept or like it over the course of the study (n = 7, including n = 3, n = 2, and n = 2 in the caffeine-free, caffeine-free and sugar-free (sparkling water), and caffeinated SD (control) groups, respectively), some children described disliking one of the drinks provided during the taste test (i.e., the sparkling water), which was reported by children to be one of the most difficult aspects of the study. Disliking properties of the study beverages (n = 7, including n = 0, n = 5, and n = 2 in the caffeine-free, caffeine-free and sugar-free (sparkling water), and caffeinated SD (control) groups, respectively) was a key barrier to adherence (Table 4), particularly among those randomized to the caffeine-free and sugar-free (sparkling water) group. In addition to the unpleasant taste of the sparkling water, several children specifically disliked not being able to identify the contents of the study beverage (n = 5), due to the opaque wrappers used for blinding.

Parents and children also described several other barriers to intervention adherence and study participation (Table 4). One theme was that children wanted to drink other SDs (n = 21, including n = 7, n = 6, and n = 8 in the caffeine-free, caffeine-free and sugar-free (sparkling water), and caffeinated SD (control) groups, respectively), besides the study beverages provided or water (which was allowed ad libitum). The desire for other beverages was particularly challenging when other SD alternatives were available and/or when peers or family members were drinking them. Despite providing the child with a number of study beverages consistent with their reported usual SD intake, a few parents noted that their child ran out of study beverages, which made adherence difficult.

Parents reported challenges in monitoring their child’s consumption of the study beverages and avoidance of other SDs. Parents found it difficult to not give in when their child asked for SDs (n = 6), especially when outside of the home. Some parents (n = 5) also alluded to the fact their child may not have fully understood the study procedures. For example, some parents mentioned their child consumed the study beverages quickly and/or set arbitrary goals to drink as many as possible in a given day, leading to excess SD intake. Parents also found the time

Table 3
Acceptability of the two-week intervention from the perspectives of participants and their parent.

Theme Subtheme	Selected Relevant Quotations ^a
Theme 1: Intervention perceived positively	
Liking the study drink	<p>“It (the study) was awesome for me because I like the drink.” (C)</p> <p>“It was a little hard [to only drink the study drink] and then when I got into it, like, every day, like, really every day doing it, [it] wasn’t that hard because I was drinking it a lot.” (C)</p> <p>“For my son it wasn’t difficult. He liked them. He really [did] drink almost all of them, but it wasn’t that difficult because he got something he liked.” (P)</p>
Enjoying the taste test	<p>“The best part was tasting all the drinks...to see which ones I like and which ones I didn’t like.” (C)</p> <p>“[My favorite part was] tasting the Coca-Cola™ (during taste test).” (C)</p> <p>“The best part of doing the study was the taste test....The test tasting and you guys and the gift cards, but for the most part hanging out with you guys.” (C)</p>
Tracking and learning about intake	<p>“[The best part] was just, [it’s] interesting to see, you know, how much he would want, and how much he would go take, and that type of thing.” (P)</p> <p>“[The best part was] seeing that she can drink other stuff besides teas and sodas.” (P)</p> <p>“[The best part was] coming here and interacting and sharing the different things that we ate and how they drank. It kinda makes you become more aware of how much you are actually drinking.” (P)</p>
Making siblings jealous	<p>“[The best part was] making my brothers jealous.” (C)</p> <p>“[His favorite part was having a drink] that his siblings cannot touch. That says a lot in a house of five kids.” (P)</p> <p>“[The best part was] having my own isolated drink.” (C)</p>
Sharing their experience	<p>“[The best part was] just sharing the experience he was having. People were just, like, ‘Wow.’ They were interested in it.” (P)</p> <p>“[My experience] was good. I enjoyed it. I enjoyed watching him enjoying it, so it made me happy.” (P)</p> <p>“[A positive thing was] that she was doing it, you know, that she wanted to, that she really wanted to do it. She was very engaged in it, like, she could talk to the people at school [about it].” (P)</p>
Feeling important	<p>“She told me that she felt excited to come in and talk to [an RA]. She felt important. She said it felt like a challenge, [and] that she really wanted to do it....She felt like she was important, like, right now (during the interview) she feels like she’s on the news.” (P)</p> <p>“[The best part was] watching them challenge themselves and trying not to drink the other sugary beverages, as opposed to drinking the sparkling water....They were, like, really trying not to let themselves down.” (P)</p> <p>“I think they enjoyed the fact that they got to drink something different from what we were drinking and that it was just theirs...something different.” (P)</p>
Feeling committed	<p>“I believe they offered him juice at a birthday party, and he declined....He was really committed to not drinking anything besides water or milk....That was really impressive for me because they’re kids.” (P)</p> <p>“I’ve been having problems with him because he likes sugar, [but] he was okay. He[’d] say ‘Okay, I have to follow the rules.’ He [took] care of it. He[’d] say, you know, ‘No, I can’t eat [that] or I can’t drink that.’” (P)</p> <p>“She did better than I expected really....I thought she was going to be trying to sneak and get juice, but she wasn’t. I think she liked doing it.” (P)</p>
Liking the study perks	<p>“[The best part was that] she got to order her own stuff [due to receiving gift cards at the end of each visit].” (P)</p> <p>“[The best part was] the Amazon gift card, ‘cause I, I used to get, like, my mom would order me Slime and she’s gonna order me a microphone.” (C)</p> <p>“[The best part was] having something for him to drink, so I didn’t have to worry about having soda in the house for two weeks.” (P)</p>
Theme 2: Taste test perceived negatively	
	<p>“The hardest part was drinking that seltzer water...because it was clear, fizzy, and didn’t taste good.” (C)</p> <p>“[I didn’t like] the flavor [of drink #2]. It didn’t actually have flavor.” (C)</p> <p>“The taste testing was the hardest part...I think it was #2 that had a very bad taste.” (C)</p>

^a Child responses are reflected by (C) following the quotation. Parent responses are indicated with (P) following the quotation.

Table 4
Challenges to intervention adherence reported by participants and their parent.

Theme Subtheme	Selected Relevant Quotations ^a
Theme 1: Disliking the study drink	
	<p>“He didn’t like the taste of it....Yeah, I think it was hard just with the other option of water.” (P)</p> <p>“It was super-duper hard because I didn’t like that drink...I don’t know why I don’t like it, [it’s] too nasty. Naaaasty.” (C)</p> <p>“[I like regular water better] because it doesn’t have sparkles (bubbles) in it, and it doesn’t have any taste.” (C)</p>
Theme 2: Disliking not knowing what they are drinking	
	<p>“[I’d pick water over the study drink because] with the water I could see what I was drinking. It’s kinda, like, if you don’t see what you’re drinking you don’t want it, ’cause you don’t know what’s in it, what it is, or whatever.” (C)</p> <p>“She really wanted to take that tape off the cans so bad, just to see what it was, ’cause I guess she got used to drinking it, you know? She wanted to see what exactly...it was.” (P)</p> <p>“Most of the time if he was drinking them...with the duct tape around it, people were just looking at us, like, ‘What is that?’ and I had to explain everywhere we go, like, ‘Oh, my son is doing a study.’” (P)</p>
Theme 3: Desiring other drinks	
Getting tired of study drink	<p>“I could tell she was getting a little bit tired of it (the study drink) as the days were, like, towards the last couple of days.” (P)</p> <p>“She’s saying it got normal, but she got tired of them. She got to the point she was like ‘Ugh,’ you know, like, ‘Ugh, not one of those.’” (P)</p> <p>“It was hard because I had to drink one drink for two weeks, and I couldn’t drink like orange juice and stuff.” (C)</p>
Wanting different drinks	<p>“It was difficult because most of the time we...have to remind him that he had to stick to the drinks that we had. He always wanted something else.” (P)</p> <p>“[The hardest part was] he wanted to drink other stuff.” (P)</p> <p>“The hardest part was that I wanted drinks that I usually drink.” (C)</p>
Theme 4: Environmental factors that increased desire for other sugary and/or caffeinated drinks	
Seeing peers consume other drinks	<p>“He doesn’t like coffee, but at church they always make coffee and the kids, they are drinking coffee, so he said ‘I want to drink a little bit’ It’s because he saw the other kids drinking coffee, so he want[ed] the same.” (P)</p> <p>“She kept wanting to drink what we were drinking. [But] obviously we couldn’t drink that (the study drink) and she couldn’t drink our things.” (P)</p> <p>“[The hardest part was], well, my siblings. When my momma’s not there and there’s juice...all of them are drinking it except for me...and they kept rubbing it in and saying ‘I have juice, I have juice!’” (C)</p>
Availability of other drinks	<p>“[It was] pretty hard because when we bought some [drinks] I wanted to drink them, but I couldn’t. I had to drink the study drinks.” (C)</p> <p>“He was like, ‘No, I’ll take an orange,’ ‘I’ll take this,’ [or] ‘I want that’....There were a lot of times that he was trying to be sneaky and [would] try to sip something. It was hard because...if we go out, he could not [have other drinks]. He had to stick to water.” (P)</p> <p>“When I saw drinks that weren’t my study drink, I really wanted those drinks.” (C)</p>
Theme 5: Not having the study drinks available	
	<p>“It (running out) happened twice, but it kinda, like, ran into us coming in the next day, so it was just, like, [you’ll have to] drink more water till you come in...to get more soda.” (P)</p> <p>“It was pretty challenging...because we actually took the sodas and we would forget them in the car, and he would get thirsty and we would have to go all the way downstairs and get them out the back of the car.” (P)</p> <p>“I think it was hard just with the other option of water...especially if we were out somewhere and they didn’t have enough of their drink They would want other drinks.” (P)</p>
Theme 6: Misunderstanding the study procedures	
	<p>“[The difficult part was] just watching [the child] just going for it, you know? [With the drinks] kind of being so readily available with so many in the house at once.” (P)</p> <p>“We’d be on the bus [and] I’d be like, ‘Wake up...you were just bouncing around.’ It was just more of a burnout, like, sodas back to back...two sodas...[and] then half an hour later he would ask for another.” (P)</p> <p>“[I drank them quickly] so I could finish the soda...finish the week...[and] get back to my Slurpee day.” (C)</p>
Theme 7: Having difficulty monitoring child adherence	
Keeping an eye on the child	<p>“We had to keep an eye on him Some days, you know, we couldn’t like keep up seeing how much he would drink in the day.” (P)</p> <p>“[The hardest part was] to have control of him.” (P)</p> <p>“He was sneaking everything. He will go get it (other sugary drinks) if I’m not looking.” (P)</p>

(continued on next page)

Table 4 (continued)

Theme Subtheme	Selected Relevant Quotations ^a
Enforcing and saying no	<p>"[The hardest part was], like, not giving in... like, I should have just said, 'No,' when they wanted the other drinks, but it's harder than you think." (P)</p> <p>"At church they have all kinds of beverage[s]. So, there [I] have [a] problem with him. I say, 'No, you can't,' [but] they have chocolate milk [and] vanilla milk." (P)</p> <p>"It was really hard when it was a birthday party... When they were passing out the juice I said I couldn't have juice, but they still gave me juice [so]...I gave it to my friend." (C)</p>
Remembering the study instructions	<p>"[The] hardest part was remembering that he was doing the study, [like], when he grabs something that wasn't the beverage or when the sodas weren't out." (P)</p> <p>"[The hardest part was] making sure that I'm consistent with it and the rules ... Sometimes you forget that you're doing the study...especially grocery shopping and him asking if he can drink stuff." (P)</p> <p>"[The hardest part was] making sure everyone was drinking their drinks." (P)</p>
Theme 8: Finding time for the study	
Completing daily questionnaires	<p>"[The hardest part was] keeping track. The survey part [especially] because he was with his grandmother a lot of the time, so we would have to call over the phone ... Sometimes, 'cause I got off [work] late, we missed a few surveys because of that." (P)</p> <p>"For me, the hardest part was the survey. Because, because, every time you finished the, like, it would be like 8, 9, [or] 10 and I'm like, 'Oh my goodness!' trying to get it over with." (C)</p> <p>"On Saturday it was difficult for me [to do the questionnaire] because sometimes I came home very late from church and I'd go 'Oh, I'll do it tomorrow.'" (P)</p>
Commuting to and from GW	<p>"[The hardest part was] coming here." (P)</p> <p>"[The hardest part was], well, it takes a long time." (C)</p> <p>"I would say the parking [was the hardest part]. Just getting here...commuting over. The traffic was rough." (P)</p>

^a Child responses are reflected by (C) following the quotation. Parent responses are indicated with (P) following the quotation.

required for study participation to be an inconvenience, particularly with regard to finding the time and/or remembering to complete the daily questionnaires (n = 2) and travel to and from GW during peak commuting hours (n = 5). However, the burden of questionnaire completion was described as "not that bad," because it only required a few minutes.

Children and parents described various strategies to overcome the aforementioned barriers and facilitate continued adherence to the study procedures (Table 5). An emergent theme was that children preferred consuming the study beverage cold or over ice, or when poured into a cup (instead of from the can). Many parents (n = 16) also reported creating an environment conducive to adherence, such as having a system to ensure that their child could easily access the study beverages or modeling behaviors consistent with the study procedures (e.g., restricting their own SD intake and/or removing SDs from their home).

4. Discussion

Our findings demonstrate that it is feasible to identify, recruit, and retain children who habitually consume large quantities of SDs (an average of 35 ounces of SDs, equivalent to approximately three cans of soda, per day) in a RCT requiring replacement of usual SD consumption with caffeine-free and/or unsweetened alternatives. Our results also support the feasibility of the intervention, with high rates of adherence to questionnaire completion observed despite the relatively high intensity of the study procedures (e.g., daily questionnaire completion, three in-person study visits over a two-week period). Feedback regarding study participation was overall positive and qualitative findings demonstrate overall high acceptability of the RCT to both child participants and their parents, irrespective of randomized treatment group, which may have been enhanced by the financial incentive provided at each of the study visits. Unsurprisingly, adherence to beverage assignments was highest in those randomized to continue caffeinated SD consumption (control group) and lowest among those randomized to consume caffeine-free and sugar-free beverages (sparkling water group), consistent with children in the sparkling water group describing that they did not like the taste of the study beverages during the qualitative interviews. Adherence to beverage consumption in the caffeine-free group, however, was significantly lower than in the caffeinated SD group, and most comparable to that observed in the caffeine-free and sugar-free (sparkling water) group. This is noteworthy given that while the majority of participants reported a preference for caffeinated and caffeine-free SDs compared with sparkling water during taste tests, preferences for caffeinated SDs compared with caffeine-free SDs were mixed. Lower adherence among those randomized to consume caffeine-free SDs compared with the control is therefore unlikely to be explained by the taste of the beverages and may be attributable to the removal of caffeine, which warrants further study.

One of the most striking findings was the high rate of retention among study participants who enrolled. All but one participant completed the two-week study, and all but two participants provided complete data at all three study visits. This is particularly noteworthy given that all of the participants were from minority and low-income backgrounds, both of which predict attrition from research studies [24]. High retention and completion rates may be, in part, explained by maintaining frequent contact with parents throughout the study and providing monetary incentives after the completion of each study visit. Furthermore, the primary method of participant recruitment was through schools and community organizations likely to be trusted by participants, which may have facilitated rapport building between participants and the study team and bolstered retention. Flexibility in the timing of the study visits was also provided to accommodate participant schedules, with the majority of the visits taking place between 5PM and 7PM. Having two bilingual student RAs on our research team was critical to reaching Spanish-speaking families at community events and integral to obtaining informed consent from

Table 5
Strategies reported by children and their parent to encourage intervention adherence.

Theme	Selected Relevant Quotations
Theme 1: Drinking the study drink in different ways	<p>"We would have [or] get ice and pour the [study] drink in it." (C)</p> <p>"Once she got the fact that hers could get cold it made hers a little easier When it was warm, she did not like it, but once it was cold, she was cool. She liked it better." (P)</p> <p>"When I could see it, yeah, I felt better about it." (C)</p>
Theme 2: Having the study drink accessible	<p>"You just had to remember, like...if I knew we were going out I tried to take a couple [study drinks] with me because I know sometimes when you're out you'll stop somewhere [and] you'll get something to drink So, we'd have them with us." (P)</p> <p>"I would provide him with the drink. So, I would, if I didn't forget, I would bring two upstairs, or he would have one." (P)</p> <p>"Once they had their designated spots in the refrigerator, everyone was good after that. We were fine. No issues." (P)</p>
Theme 3: Informing others of child's participation	<p>"At school they know, [so] he couldn't drink it. So, in school they stopped it." (P)</p> <p>"I explained to his grandmother that we were just gonna stick to these sodas, so he just stuck with these or water or milk." (P)</p> <p>"Their teachers were informed that they couldn't drink any juices or soda." (P)</p>
Theme 4: Modeling lower consumption	<p>"This experiment was difficult for everybody...even me. No soda, nothing, so my kids will not have that. My house is only these two, so if I don't drink, they don't drink." (P)</p> <p>"As far as sweet drinks, I know I could do better because I, [or] they can't drink if I don't buy it because they're not going out to a grocery store to buy it." (P)</p> <p>"I couldn't drink. I used to drink 3 or 4 cups a day [but I didn't during the study] to support him." (P)</p>

¹Child responses are reflected by (C) following the quotation. Parent responses are indicated with (P) following the quotation.

Spanish-speaking parents, which, in turn, may have positively contributed to our recruitment efforts and retention of a diverse sample. Enrollment of the child participants, however, was limited to those who were fluent in English because the bilingual research team members were only available on a part-time basis and unable to be present for all interactions with a given participant considering the intensive and longitudinal nature of the data collection.

Study participation was viewed positively by both children and parents. Daily questionnaire completion was manageable, and for some, even enjoyable. While drinking only the assigned study beverages or water was difficult for many participants, especially those randomized to caffeine-free and sugar-free beverages (sparkling water), children enjoyed the challenge and were committed to adherence with beverage instructions. Although most children randomized to consume caffeine-free and sugar-free beverages reported disliking the taste of sparkling water, adherence was maintained by children consuming only plain water (also caffeine-free and sugar-free) and avoiding all other SDs. Nonetheless, the widely reported distaste for sparkling water suggests that provision of diet beverages with artificial sweeteners may offer a more palatable, option for caffeine-free and sugar-free replacement beverages. We had decided not to provide diet beverages with artificial sweeteners, however, because artificial sweeteners activate the central reward system, albeit to a lesser extent than caloric sugars [25]. And, our prior work has demonstrated that many parents do not view artificial sweeteners as safe for their children to consume [26].

Even among children randomized to continue consumption of SDs, whether caffeinated or caffeine-free, the lack of variety of the assigned beverages was a commonly described barrier to adherence. This suggests that it may be necessary to provide participants with a combination of beverages in future studies in accordance with their randomization (e.g., different types of caffeinated, caffeine-free, or unsweetened beverages). For example, assigned beverages could be closely matched to the taste of the SDs habitually consumed so that a participant who typically drinks Pepsi™ (caffeinated) daily along with Sprite™ (not caffeinated), and Fanta™ (not caffeinated) and is randomized to the caffeine-free group, could be provided with caffeine-free Pepsi™, Sprite, and Fanta™, in a blinded fashion. If the same child in this example was randomized to the caffeine-free and sugar-free group, diet caffeine-free Pepsi™, Sprite Zero™, and Fanta Zero™ could hypothetically be provided instead of different varieties of sparkling water. However, ongoing uncertainty in the scientific community surrounding the metabolic and health effects of artificial sweeteners among children [27], along with the aforementioned view of many parents that artificial sweeteners are not safe for their children to consume [26], may pose barriers to provision of diet beverages.

The inconvenience of traveling to and from study visits suggests that conducting the study procedures at community locations in proximity to where participants live may further enhance participant satisfaction. The inconvenience was likely exacerbated by scheduling visits after usual school and work hours, albeit per participants' preferences, because these time periods also coincided with peak commuting hours in a high-traffic metropolitan area. Community-based follow-up may be particularly important for maintaining high rates of retention in RCTs of longer duration.

Incorporation of strategies reported by the children and parents into intervention materials for future studies is likely to further enhance adherence and reduce the burden associated with study participation. Particularly noteworthy were some parents' reporting that they removed SDs from the home and/or modeled avoidance of SDs during the RCT. While this may not be practical for all parents, parent modeling is a well-described driver of children's beverage intakes [28,29] and could be suggested as a strategy by the research team at the time of randomization. Furthermore, positive changes to the home food environment as a result of study participation may be continued following study completion and may encourage sustained reductions in SD consumption [28,29].

Parents also described a variety of relatively simple solutions that they independently devised to ensure that study beverages were available and accessible to their child during the study, which would likely be useful for future participants. A key theme was planning ahead for situations where adherence was most difficult, such as bringing a cooler with the study drinks when out of the home for an extended period of time. In addition, designating a specific location for the child to access the study drinks reduced the likelihood that they would inadvertently choose other SDs and also served to instill in the child a feeling of ownership surrounding their beverage consumption behaviors.

Strengths of this feasibility and acceptability study include the diverse sample with respect to race/ethnicity and the high rates of completion and retention. Our approach was further strengthened by the ability to collect daily assessments of withdrawal symptoms and beverage consumption over a two-week period and the use of mixed methods to measure intervention feasibility and acceptability. However, this study was limited by the small sample size and the relatively short duration of the intervention. It is also not possible to determine whether any strategies for avoiding SDs used during the intervention were sustained, because no follow-up assessments were performed after study completion. Another important limitation is the possibility of social desirability bias that may have led to more positively skewed parent and child responses when reporting their study experiences during the interviews. Additionally, high study acceptability may be explained by the financial compensation provided, as well as selection bias, as those who volunteered to participate were highly motivated and thus may not be reflective of the larger population of children who consume caffeinated SDs daily and their parents.

Taken together, our findings support the feasibility and acceptability of this pilot RCT and bode positively for the design and execution of similar interventions to investigate development of withdrawal symptoms in response to caffeinated SD cessation in children. Larger and longer-term studies are needed to robustly examine whether restriction of added sugar and/or caffeine in SDs results in withdrawal symptoms among children. Development of withdrawal symptoms may pose a barrier to sustained reductions in children's SD intake and may vary across individuals, allowing for identification of subsets of children who may find SD reduction to be particularly challenging. Minor modifications to the intervention materials and study protocol, based on the participant feedback described, will inform the design and conduct of a subsequent trial with a larger sample size and a longer intervention duration.

Author contributions

ACS, AJV, KDE, WHD, and JS designed the study. ACS, EFB, SH, and KC transcribed, coded, and analyzed the data. ACS wrote the first draft of the manuscript. All authors were involved in editing and revising the manuscript and approved the submission of this article to *Contemporary Clinical Trials Communications*.

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Declaration of competing interest

None of the authors have any competing interests to declare.

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