

Complete Title: Impact of Sugar-Sweetened Beverage Health Warnings

Short Title: Impact of Sugar-Sweetened Beverage Health Warnings

Sponsor: University of North Carolina, Chapel Hill

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Sponsor: University of North Carolina, Chapel Hill
Chapel Hill, NC 27514

United States

Study Principal Investigator: Anna H. Grummon

Department of Health Behavior

135 Dauer Drive, 302 Rosenau Hall CB 7440

Chapel Hill, NC 27599

Phone 650-644-7366

email: agrummon@unc.edu

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Lead Investigator:
Anna H. Grummon, MSPH
University of North Carolina at Chapel Hill
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I confirm that I have read this protocol and understand it.

Principal Investigator Name: Anna H. Grummon

Principal Investigator Signature: 

Date: April 30, 2018

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ABBREVIATIONS

| Abbreviation | Definition |
|---------------------|--------------------------|
| B-Lab | Behavioral Lab |
| BMI | Body mass index |
| CVD | Cardiovascular disease |
| FOP | Front-of-package |
| OLS | Ordinary least squares |
| SSB | Sugar-sweetened beverage |
| T2D | Type 2 diabetes |

PROTOCOL SYNOPSIS

| | |
|---------------------------|---|
| Study Title | Impact of Sugar-Sweetened Beverage Health Warnings |
| Funder | North Carolina Translational and Clinical Sciences Institute; University of North Carolina Department of Family Medicine |
| Clinical Phase | NA |
| Study Rationale | <ul style="list-style-type: none"> • Sugar-sweetened beverage (SSB) consumption is a major contributor to obesity, diabetes, and cardiovascular disease. • To reduce SSB consumption, state and local legislators have proposed requiring SSB containers to bear front-of-package (FOP) labels with health warnings – explicit messages about the health harms of consuming SSBs. To date, there are few studies assessing whether such warnings influence consumer behaviors. • This study aims to evaluate the effect of SSB health warnings on sugar-sweetened beverage purchases and secondary outcomes using a randomized controlled trial in a naturalistic setting. |
| Study Objective(s) | <p>Primary</p> <ul style="list-style-type: none"> • To evaluate the effect of sugar-sweetened beverage health warnings on total calories of sugar-sweetened beverages purchased. <p>Secondary</p> <ul style="list-style-type: none"> • To evaluate the effect of sugar-sweetened beverage health warnings on: <ul style="list-style-type: none"> ○ Number of calories purchased from all foods and beverages ○ Proportion of participants who purchased a sugar-sweetened beverage ○ Number of sugar-sweetened beverages purchased ○ Mean intentions to limit consumption of beverages with added sugar ○ Mean intentions to limit consumption of specific sugar-sweetened beverages ○ Proportion of participants who noticed trial labels ○ Mean attention to trial labels ○ Mean emotional reactions to trial labels ○ Mean cognitive elaboration ○ Social interactions about the trial label ○ Mean perceptions of added sugar content in specific sugar-sweetened beverages ○ Mean attitudes toward specific sugar-sweetened beverages ○ Mean product attitudes toward specific sugar-sweetened beverages ○ Mean outcome expectations regarding consumption of sugar-sweetened beverages |

| | |
|---|---|
| Test Article(s) <i>(If Applicable)</i> | This study evaluates the effects of exposure to a textual sugar-sweetened beverage health warning label compared to exposure to a control label. Labels are applied to the the front-of-package of sugar-sweetened beverage containers. |
| Study Design | Single-center, single-blind, two-arm randomized controlled trial evaluating the effects of SSB health warnings. |
| Subject Population key criteria for Inclusion and Exclusion: | <p>Inclusion Criteria</p> <ol style="list-style-type: none"> 1. Age 18 and older 2. Consume at least 1 serving (12 ounces) of sugar-sweetened beverages per week 3. Able to read and write in English <p>Exclusion Criteria</p> <ol style="list-style-type: none"> 1. Under the age of 18 2. Consume less than 1 serving (12 ounces) of sugar-sweetened beverages per week 3. Unable to read and/or write in English |
| Number of Subjects | 400 |
| Study Duration | Each subject's participation will last approximately 30 minutes. The enrollment period is expected to last ~6 months. |
| Study Phases | <p>There are two phases:</p> <ol style="list-style-type: none"> (1) <u>Screening</u>: screening for eligibility and obtaining consent and (2) <u>Intervention</u>: study intervention/experimental treatment. |
| Efficacy Evaluations | The primary outcome is the total number of calories from sugar-sweetened beverages the participant purchases during the study shopping task, calculated as the sum of calories/container across all sugar-sweetened beverages in the participant's basket at the completion of the shopping task. |
| Statistical and Analytic Plan | <p>Primary outcome</p> <ul style="list-style-type: none"> • We will use ordinary least squares (OLS) regression to examine whether the primary outcome differs by trial arm, controlling for any participant characteristics found to be unbalanced across trial arms in balance tests. The coefficient on the trial arm indicator variable is the primary effect estimate, and gives the average difference in (adjusted) means between the treatment arm and the control arm. It is interpreted as the impact of SSB health warnings on total calories of sugar-sweetened beverages purchased. <p>Secondary outcomes</p> <ul style="list-style-type: none"> • We will use OLS regression, logistic regression, and Poisson regression to examine whether continuous, dichotomous, and count secondary outcomes differ by trial arm, respectively. |
| Data and Safety Monitoring Plan | <ul style="list-style-type: none"> • The principal investigator is responsible for data quality management and ongoing assessment of safety. |

1 BACKGROUND AND RATIONALE

Obesity, diabetes, and cardiovascular disease are among the leading causes of death in the United States.¹ Consumption of sugar-sweetened beverages (SSBs) such as sodas, fruit drinks, and sports drinks, is a significant contributor to these preventable conditions.²⁻⁶ Despite the health risks of SSB consumption, the average American adult drinks a remarkable 40 to 50 gallons of SSBs every year, accounting for seven percent of daily caloric intake.⁷⁻⁹ To reduce SSB consumption, state and local legislators have proposed requiring SSB containers to bear front-of-package (FOP) labels with health warnings – explicit messages about the health harms of consuming SSBs.¹⁰⁻¹⁵ Despite policymakers’ interest in SSB health warnings, there remain critical gaps in our knowledge of whether and how such warnings change behavior.

Theoretical and empirical work suggest that SSB health warnings are a promising strategy for reducing consumption. Studies of similar textual health warnings on cigarette packs find that warnings reduce smoking in adolescents.¹⁶ Likewise, online randomized trials find that SSB health warnings reduce intentions to purchase SSBs among adolescents,¹⁷ young adults,¹⁸ and parents.¹⁹ In turn, intentions strongly predict behaviors,²⁰ and survey research has shown that intentions to consume SSBs are associated with actual SSB consumption.²¹⁻²³ While this evidence is suggestive, almost no studies have examined whether SSB health warnings change actual behaviors. Answering this question is essential: if effective, SSB health warnings are a highly scalable, low-cost intervention that could reduce SSB intake and chronic disease.

This study aims to evaluate the effects of SSB health warnings on SSB purchases and secondary outcomes using a randomized controlled trial in a naturalistic setting. This Protocol and Statistical Analysis Plan is being submitted as an attachment to the study’s trial registration (NCT #03511937) prior to analysis. The protocol describes the trial objectives, design, and population. The analysis plan pre-specifies planned analyses of the primary, secondary and other outcomes, prior to examining the data. In writing the protocol and statistical analysis plan, we have adhered to the guidelines set forth by Gamble et al.,²⁴ with minor modifications as needed based on trial design.

1.1 Introduction

This is a single-center, single-blind, two-arm randomized controlled trial evaluating the effects of SSB health warnings.

Setting. The trial is conducted in a “mock store” at the Fuqua Behavioral Lab (“B-Lab”), located at the Duke Fuqua School of Business in Durham, North Carolina, United States. The B-Lab mock store was developed for researchers to examine the influence of store and product characteristics on consumer behavior in a realistic but controlled environment. The mock store resembles a convenience store.

Products for sale. Beverages for sale in the mock store include a variety of SSBs and non-SSBs. To select specific beverages to sell, we examined electronic purchase data²⁵ from households in North Carolina to identify popular products by volume purchased in each of the following categories of SSBs: sodas; fruit drinks; sports drinks; energy drinks; ready-to-drink coffees; ready-to-drink teas; and flavored waters (**Table 1**). We then identified non-SSBs that most closely matched the selected SSBs (e.g., if a particular flavor and brand of soda was selected for sale in the store, we also selected the diet version of this soda to sell). For fruit drinks, we selected the 100% fruit juices that most closely matched the fruit drink selected (e.g. we selected 100% cranberry juice to match the cranberry juice cocktail fruit drink). To more fully reflect the beverage retail environment, we also elected to sell plain bottled water and non-calorically flavored sparkling water, despite these beverages having no corresponding SSB.

In each beverage category, the store sells at least one variety (i.e., one brand/flavor) of the SSB (and therefore at least one variety of the matched non-SSB). We elected to sell five varieties of sodas and two varieties of fruit drinks to reflect that more calories of SSBs come from these categories than from other SSB categories.²⁶ Beverages are 8.0 to 20.0 fluid ounces per container. Non-SSBs are matched to their corresponding SSB in container size.

Non-beverage items for sale include foods (e.g., chips, crackers, cookies, pre-packaged fruits, nuts, canned soups, pasta, cereal, candy) and household products (e.g., shampoo, soap, toothpaste, paper towels, notebooks, garbage bags). These products were selected by the B-Lab to interest participants and mimic a typical convenience store setting.

Table 1. Beverages sold in the trial mock store

| Category | Sugar-Sweetened Beverage | Non-Sugar-Sweetened Beverage |
|------------------------|--|--|
| Sodas | Regular (non-diet) carbonated soft drinks and sodas | Diet carbonated soft drinks and sodas |
| Fruit drinks | Fruit-flavored drinks and juice drinks that are not 100% juice | 100% fruit juices |
| Sports drinks | Regular (non-diet) sports drinks | Diet or low-calorie sports drinks |
| Energy drinks | Regular (non-diet) energy drinks | Diet or low-calorie energy drinks |
| Ready-to-drink coffees | Pre-packaged sweetened coffee | Pre-packaged unsweetened coffee |
| Ready-to-drink teas | Pre-packaged sweetened tea | Pre-packaged non-calorically sweetened tea |
| Waters | Calorically-sweetened flavored waters | Plain (unflavored) waters and non-calorically sweetened waters |

Pricing. To control for the potential influence of price on participants' purchases, prices are held constant across trial arms. Following others,²⁷ we set beverage prices based on standard retail prices per ounce in grocery and convenience stores surrounding the laboratory. Prices are \$1.46 USD for all beverages except for coffees and energy drinks, which are \$2.26 USD, reflecting their higher retail price. All SSBs and their matching non-SSB were priced identically (e.g., regular and diet sodas were the same price; regular and diet energy drinks were the same price). Prices for non-beverage items remained at the levels set previously by the B-Lab, which had been selected to mimic real-world prices.

1.2 Description of Trial Arms (Intervention)

Participants are randomly assigned to one of two arms: a “health warnings” arm (intervention) or a control arm. In the health warnings arm, all SSBs are labeled with a health warning label. The health warning label is a 1.5” octagon with red background, a white border, and white text (**Figure 1**). The text reads: “WARNING Beverages with added sugar contribute to tooth decay, diabetes, and obesity.” All text is in Arial font. The word “WARNING” is in 12-point font and the remaining text is in 9.25-point font. The words “WARNING,” “tooth decay,” “diabetes,” and “obesity” are bolded. In the control arm, all SSBs are labeled with a control label. The control label is a 1” x 2.625” rectangle label with white background and a black barcode image (Figure 1). In both arms, labels are adhered directly on the front-of-package

(FOP) of SSB containers. The location of the label on the containers' packaging is held constant across trial arms (i.e., both the health warning label and the control label are placed on the same location on the product's FOP). However, this location on the FOP varies slightly across beverage types based on the shape and size of the container.



Figure 1. Health warning label (left) and control label (right) (actual sizes).

1.3 Study Findings (Risk and Benefits)

Health warnings on SSB are a promising strategy for reducing SSB consumption and the associated health risks. Studies of similar textual health warnings on cigarette packs find that warnings reduce smoking in adolescents,¹⁶ and pictorial health warnings on cigarettes have been shown to increase quit attempts in adults.²⁸ Likewise, online randomized trials find that SSB health warnings reduce intentions to purchase SSBs among adolescents,¹⁷ young adults,¹⁸ and parents.¹⁹ In turn, intentions strongly predict behaviors,²⁰ and survey research has shown that intentions to consume SSBs are associated with actual SSB consumption.^{21–23} While this evidence is suggestive, almost no studies have examined whether SSB health warnings change actual behaviors. Answering this question is essential: if effective, SSB health warnings are a highly scalable, low-cost intervention that could reduce SSB intake and chronic disease. This research will provide timely information on this important gap in our understanding of the effects of SSB health warnings.

Risks of participating in this study are minimal. One risk is that participants may find that some questions on the survey make them bored or uncomfortable. To minimize this risk, the study duration is short (~30 minutes) and questionnaire items do not query sensitive topics. There is also a small risk of loss of privacy resulting from accidental disclosure of study data.

Not only is this risk small, but the consequences of a rare accidental disclosure would also be small, as data collected pertain to beverage consumption, attitudes about beverages, demographic characteristics, and choice of products to purchase from a mock store setting. If these data were disclosed, they would not affect insurability, social standing, or employment. In this way, data collected by the study do not pose any risk greater than what participants encounter in their daily life.

1.4 Relevant Literature and Data

SSB consumption is a public health problem. On any given day, half of American adults consume a sugar-sweetened beverage (SSB),²⁶ and one in seven are considered ‘heavy SSB consumers’ (intake > 500 calories/day).²⁹ While some studies have reported declines in caloric intake from SSBs since 2003, these declines seem to be leveling off in recent years.^{8,26} Further, at more than one serving per day, average SSB consumption among American adults remains well above the recommendations set forth in national dietary guidelines.^{30,31} Across all food and beverage categories, SSBs remain the single largest contributor to added sugar intake³² and are the fourth largest contributor to total caloric intake.³³

These statistics are concerning because SSB consumption has been linked to several negative health outcomes including excess body weight, type 2 diabetes (T2D), and cardiovascular disease (CVD).^{2-5,34-38} Among unhealthy foods and beverages, SSBs are often singled out as particularly problematic because they are high in calories but offer little or no nutritional value,³⁹⁻⁴¹ and because the liquid calories in SSBs cause faster increases in blood sugar⁴² and lower feelings of fullness compared to solid foods.⁴³ Recently, prominent researchers have even identified SSBs as perhaps “the single largest driver of the obesity epidemic.”^{40(p1805)} Indeed, a meta-analysis of prospective cohort studies estimated that consuming an additional one serving (12 ounces) of SSBs per day is associated with a 0.12-0.22 kg increase in weight over the course of a year,² and randomized controlled trials suggest the relationship between SSB consumption and weight gain may be even stronger (as high as 2.70 kg/year for an additional serving of SSBs/day).^{38,44}

SSB consumption also increases risk of T2D and CVD, both indirectly via its influence on obesity (a known risk factor for poor cardiometabolic outcomes) and directly via its effects on metabolic and inflammatory processes.^{3,4} A recent meta-analysis of prospective studies including

more than 310,000 adults found that individuals in the highest quantile of SSB consumption (1-2 servings/day) had 26% greater risk of developing T2D than those in the lowest quantile (no consumption or <1 serving/month).³⁵ In a separate meta-analysis of 17 cohort studies representing more than 10 million person-years, Imamura et al. estimated that 8.5% of T2D cases in the United States could be attributed to SSB consumption.⁴ Likewise, data are accumulating to suggest that SSB consumption increases risk of cardiovascular problems including hypertension, inflammation, adverse lipid profiles, and coronary heart disease.^{3,45-47}

SSB health warnings are a promising policy option for reducing SSB purchases and consumption. To reduce SSB consumption and the burden of SSB-related chronic diseases, legislators in at least five states and several major cities have proposed requiring SSB containers to bear labels with health warnings.¹⁰⁻¹⁵ While few studies have examined whether SSB health warnings influence consumer behavior, three randomized trials have demonstrated that health warnings significantly reduce purchase intentions.¹⁷⁻¹⁹ In turn, several theories of health behavior, including the Theory of Planned Behavior, posit that intentions are a key determinant of behaviors.^{20,48-50} Cross-sectional studies find that intentions to consume SSBs are positively associated with actual SSB consumption among adolescents,^{22,23} and that intentions to limit SSB consumption are negatively related to SSB consumption in adults.²¹ Together, these studies provide support for examining the effects of SSB health warnings on SSB purchases.

SSB health warnings may also influence psychological outcomes. To date, the mechanisms through which health warnings influence SSB consumption are largely unknown. However, theories of health behavior suggest plausible mediators, including knowledge,^{51,52} attitudes,²⁰ and outcome expectations.⁵³⁻⁵⁵ Online studies have documented that SSB health warnings influence these variables.^{17,19} Additionally, recent research on pictorial tobacco health warnings indicates that three important mediators of the effect of warnings on smoking behavior are warning reactions, including attention to the warnings, cognitive elaboration (thinking about the warnings), and affective message reactions (fear, worry).^{56,57} These studies provide support for examining the effects of SSB health warnings on psychological outcomes such as knowledge, attitudes, outcome expectations, attention, cognitive elaboration, and affective reactions. Specific measures this study uses to assess these constructs are described in Section 5 below.

2 STUDY OBJECTIVE

The primary objective of this trial is to evaluate the effect of SSB health warnings on total calories of SSBs purchased. We hypothesize that exposure to SSB health warnings will reduce calories of SSBs purchased. The secondary objectives are to evaluate the effect of SSB health warnings on the following secondary outcomes:

- Number of calories purchased from all foods and beverages
- Proportion of participants who purchased a sugar-sweetened beverage
- Number of sugar-sweetened beverages purchased
- Mean intentions to limit consumption of beverages with added sugar
- Mean intentions to limit consumption of specific sugar-sweetened beverages
- Proportion of participants who noticed trial labels
- Mean attention to trial labels
- Mean emotional reactions to trial labels
- Mean cognitive elaboration
- Social interactions about the trial label
- Mean perceptions of added sugar content in specific sugar-sweetened beverages
- Mean attitudes toward specific sugar-sweetened beverages
- Mean product attitudes toward specific sugar-sweetened beverages
- Mean outcome expectations regarding consumption of sugar-sweetened beverages

3 INVESTIGATIONAL PLAN

3.1 Study Design

This is a single-center, single-blind, two-arm randomized controlled trial evaluating the effects of SSB health warnings. The study includes two phases:

- (1) Screening: screening for eligibility and obtaining consent and
- (2) Intervention: study intervention.

3.2 Allocation to Treatment Groups and Blinding

Participants are randomly assigned to one of two arms: a health warnings arm or a control arm. Participants have an equal chance of being randomized to either trial arm (i.e., treatment allocation was a 1:1 ratio). An independent biostatistician conducted the randomization prior to data collection. Randomization was carried out by generating a random number for each participant identification code (ID). Participant IDs were ordered on this random number from smallest to largest. The bottom half of the IDs were assigned to the control arm and the top half to the treatment arm. This procedure ensures equal group sizes. When participants arrive for their study visit, they are assigned the next consecutive participant ID and are allocated to the trial arm previously assigned to that ID.

Participants are blinded to their assigned trial arm. Specifically, they are not told the trial's purpose nor are they told information about the trial arms. The experimenter is aware of the trial arm to which the participant has been assigned.

3.3 Number of Subjects

This trial aims to enroll 400 participants (200 per arm). See Section 6.4 for information on sample size determination.

4 STUDY PROCEDURES

4.1 Screening Procedures

Eligible participants are English-speaking adults age 18 years or older who consume at least one serving (12 ounces) of SSBs per week. Participants must be willing and able to consent and comply with study procedures. This study does not employ any exclusions based on race, ethnicity, or gender. To determine eligibility, interested participants are asked to complete a brief online survey. The survey queries the prospective participant's age, usual SSB consumption (using an adapted version of the BEV-Q 15, a validated questionnaire⁵⁸), and own and parental educational attainment. Participants aged 18 years or older who consume at least 12 ounces of SSBs per week are invited to schedule a time to participate. Ineligible participants are thanked for their time.

We will track and summarize participant enrollment, allocation, and analysis using a CONSORT diagram. The diagram will report the number of participants who were:

- Assessed for eligibility
- Excluded after screening
 - Excluded because did not meet inclusion criteria
 - Excluded because declined to participate or study visit never scheduled
 - Excluded because cancelled or did not attend study visit
- Randomized
- Received allocated intervention (by treatment arm)
- Analyzed (by treatment arm)
 - Withdrawn and/or excluded from analyses (and reason for exclusion)

4.2 Experimental Procedures

The in-person study visit takes place in the Duke Fuqua Behavioral Lab (B-Lab, see above description). Participants arrive to the B-Lab at their scheduled appointment time and are greeted by the experimenter. After providing informed consent (see Section 11 below), participants are escorted to the mock store. When they arrive in the mock store, they are provided with a shopping basket and their participation incentive (\$10 USD) in cash. SSBs in the mock store are pre-labeled with the appropriate label based on the participant's assigned trial arm (health warning vs. control). Participants are instructed to pretend they are on a usual shopping trip and reminded that there are no right or wrong products to select. They are not told the trial's purpose nor are they told information about the trial arms.

Participants are asked to complete a shopping task. They are given a list of three product categories (household items, foods, and beverages, listed in this order) and are asked to select two items in each of these categories, for a total of six items. They indicate their selections by placing items in their shopping basket. Participants are instructed that, within each category, they can select the same item twice, or can select two different items (e.g., can select the same food item twice, or select two different food items). Participants are then instructed that they will be required to purchase one of the items they select, and that this item will be chosen for them at random by the experimenter. This procedure incentivizes participants to only select products they are actually interested in purchasing. The experimenter ensures the participant understands the instructions then leaves the mock store while the participant completes the shopping task.

After participants have completed the shopping task, the experimenter records what

products are in the participant's basket, then randomly selects one of the products for the participant to purchase with his or her incentive cash. The participant pays for the product and receives change as necessary. After paying for their item, the participant completes a computer-based survey in another room.

4.3 Withdrawal Procedures

Individual participants will be withdrawn from the study if they indicate they do not wish to participate (i.e., refuse or withdraw their consent), or if they cannot comply with the study procedures, such as not arriving at the laboratory to complete the shopping task or not being willing to select products in the mock store.

5 STUDY EVALUATIONS AND MEASUREMENTS

Outcome variables, organized by type (i.e., primary, secondary, other), are described in **Table 2**. Purchase variables (i.e., number of calories purchased from SSBs, number of calories purchased from all foods and beverages, proportion of participants who purchased an SSB, and number of SSBs purchased) are assessed by the experimenter, who records all of the participant's selections at the end of the shopping task. All other outcomes are assessed via participant self-report on a computer-based survey that is completed within ~30 minutes of completing the ~10-minute shopping task.

Table 2. Outcome variables.

| Outcome | Definition/Description | Timing of Assessment |
|---|--|---|
| Primary Outcome | | |
| Number of calories (kcal) purchased from SSBs | Total number of calories from sugar-sweetened beverages in the participant's basket when he/she completes the shopping task, calculated as the sum of calories/container for all SSB containers. | Immediately after the participant completes the ~10-minute shopping task. |
| Secondary Outcomes | | |
| Number of calories (kcal) purchased from all foods and beverages. | Assessed as the total number of calories from all products (including sugar-sweetened beverages, non-sugar-sweetened beverages, and all foods) in the participant's basket when he/she completes the shopping task. Total calories purchased will be calculated as the sum of calories/container for all products. | Immediately after the participant completes the ~10-minute shopping task. |

| Outcome | Definition/Description | Timing of Assessment |
|--|--|---|
| Proportion of participants who purchased a sugar-sweetened beverage | Assessed as the proportion of participants who have one or more sugar-sweetened beverage in his/her basket when he/she completes the shopping task. | Immediately after the participant completes the ~10-minute shopping task. |
| Number of sugar-sweetened beverages purchased | Assessed as the number of sugar-sweetened beverages in the participant's basket when he/she completes the shopping task. | Immediately after the participant completes the ~10-minute shopping task. |
| Mean intentions to limit consumption of beverages added sugar | Assessed using 3 items adapted from Klein, Zajac & Monin (2009). ⁵⁹ The items ask participants to rate the extent to which they want to, plan to, and are likely to, drink less than 1 beverage with added sugar in the next week. Responses to these three items will be averaged to create a mean intentions score. Response options are on a 1 to 7 scale, with higher scores indicating higher intentions to limit consumption of beverages with added sugar. | Within 30 minutes of completing ~10-minute shopping task |
| Mean intentions to limit consumption of specific sugar-sweetened beverages | Assessed using 5 items adapted from Klein, Zajac & Monin (2009). ⁵⁹ For each of the five beverage categories, participants will rate the extent to which they are likely to drink less than 1 serving of the beverage in the next week. Responses will be averaged to a create a mean intentions score. Response options are on a 1 to 7 scale, with higher scores indicating higher intentions to limit consumption of these beverages. | Within 30 minutes of completing ~10-minute shopping task |
| Proportion of participants who notice the trial labels | Assessed using 1 item adapted from Roberto et al. (2016). ¹⁹ The item asks participants to indicate whether they noticed the trial labels. Response options are 0 (no) and 1 (yes). | Within 30 minutes of completing ~10-minute shopping task |
| Mean attention to the trial labels | Assessed using 2 items adapted from Nonnemaker et al. (2010). ⁶⁰ The items ask participants to rate their agreement with statements about whether the label grabbed their attention and whether they read and looked closely at the label. Responses will be averaged to create a mean attention score. Responses are on a 1 to 5 scale, with higher scores indicating higher attention to the labels. | Within 30 minutes of completing ~10-minute shopping task |

| Outcome | Definition/Description | Timing of Assessment |
|---|--|--|
| Mean emotional reactions to trial labels | Assessed using 6 items adapted from Brewer et al. (2018). ⁶¹ The items ask participants to indicate the extent to which trial labels elicited particular emotional reactions (e.g., fear, guilt, disgust). Responses will be averaged to create a mean emotional reactions score. Response options are on a 1 to 5 scale, with higher scores indicating stronger emotional reactions. | Within 30 minutes of completing ~10-minute shopping task |
| Mean cognitive elaboration | Assessed using 2 items adapted from Moodie, MacKintosh & Hammond (2010) ¹⁶ and Fathelrahman et al. (2010). ⁶² Items ask participants to rate the amount they thought about the information conveyed by the trial label and about the health consequences of consuming beverages with added sugar. Responses will be averaged to create a mean cognitive elaboration score. Response options range from 1 to 5, with higher scores indicating more elaboration. | Within 30 minutes of completing ~10-minute shopping task |
| Social interactions about the labels | Assessed using 1 item adapted from Brewer et al. (2018). ⁶¹ Participants rate the extent to which they are likely to have social interactions about the trial label. Response options are on a 1 to 5 scale, with higher scores indicating a higher likelihood of having social interactions. | Within 30 minutes of completing ~10-minute shopping task |
| Mean perceptions of added sugar content in specific sugar-sweetened beverages | Assessed using 5 items adapted from Roberto et al. (2016). ¹⁹ For each of five beverage categories, participants rate the amount of added sugar they think is in 1 serving of the beverage. Responses will be averaged to create a mean perceptions of added sugar score. Response options are on a 1 to 4 scale, with higher scores indicating perceptions of higher added sugar content. | Within 30 minutes of completing ~10-minute shopping task |
| Mean attitudes toward consuming specific sugar-sweetened beverages | Assessed using 5 items adapted from Bollard et al. (2016). ¹⁸ For each of five beverage categories, participants rate how healthy/unhealthy it is for them to consume that beverage category. Responses will be averaged to create an mean attitudes score. Response options are on a 1 to 7 scale, with higher scores indicating more positive attitudes toward consuming these sugar-sweetened beverages. | Within 30 minutes of completing ~10-minute shopping task |

| Outcome | Definition/Description | Timing of Assessment |
|---|---|--|
| Mean product attitudes toward specific sugar-sweetened beverages | Assessed using 10 items adapted from Bollard et al. (2016). ¹⁸ For each of five beverage categories, participants rate the appeal and the coolness of the beverage category. Responses will be averaged to create a mean product attitude score. Responses are on a 1 to 7 scale, with higher scores indicating more positive product attitudes toward these sugar-sweetened beverages. | Within 30 minutes of completing ~10-minute shopping task |
| Mean outcome expectations regarding consumption of beverages with added sugar | Assessed using 4 items adapted from Roberto et al. (2016). ¹⁹ Participants will rate the extent to which they expect that consuming beverages with added sugar would increase their risk of negative health outcomes (e.g., tooth decay). Responses will be averaged to create a mean outcome expectations score. Responses are on a 1 to 7 scale, with higher scores indicating more negative outcome expectations. | Within 30 minutes of completing ~10-minute shopping task |
| Other Outcomes | | |
| Mean injunctive norms regarding consumption of beverages with added sugar | Assessed using 3 items adapted from Zoellner et al. (2012). ²¹ Items ask participants to rate the extent to which people who are important to them think they should drink less than 1 beverage with added sugar per week, would approve of them drinking less than 1 beverage with added sugar per week, and want them to drink less than 1 beverage with added sugar per week. Responses will be averaged to create a mean injunctive norms score. Responses are on a 1 to 5 scale, with higher scores indicating higher injunctive norms. | Within 30 minutes of completing ~10-minute shopping task |
| Perceived message effectiveness of trial label | Assessed using 1 item adapted from Brewer et al. (2018). ⁶⁰ Participants rate the extent to which the trial label to which they were exposed in the shopping task would discourage them from drinking beverages with added sugar. Response options are on a 1 to 5 scale, with higher scores indicating higher perceived message effectiveness. | Within 30 minutes of completing ~10-minute shopping task |
| Support for sugar-sweetened beverage health warning labels | Assessed using 1 item adapted from Brewer et al. (2018). ⁶⁰ Participants rate their support for a policy that would require health warning labels on sugar-sweetened beverages. Responses are on a 1 to 4 scale, with higher scores indicating greater support. | Within 30 minutes of completing ~10-minute shopping task |

| Outcome | Definition/Description | Timing of Assessment |
|--|--|--|
| Mean self-efficacy to limit consumption of beverages with added sugar | Assessed using 3 items adapted from Brewer et al. (2018). ⁶⁰ Items ask participants to rate the extent to which: it would be easy to drink less than 1 beverage with added sugar per week; they have the ability to drink less than 1 beverage with added sugar per week; and they are confident that they could drink less than 1 beverage with added sugar per week. Responses will be averaged to create a mean self-efficacy score. Responses are on a 1 to 5 scale, with higher scores indicating self-efficacy. | Within 30 minutes of completing ~10-minute shopping task |
| Mean response efficacy of limiting consumption of beverages with added sugar | Assessed using 5 items adapted from Brewer et al. (2018). ⁶⁰ Participants indicate the extent to which drinking no beverages with added sugar would lower their chances of weight gain, diabetes, tooth decay, and heart disease, and the extent to which drinking no beverages with added sugar would improve their health. Responses will be averaged to create a mean response efficacy score. Responses are on a 1 to 5 scale, with higher scores indicating greater response efficacy. | Within 30 minutes of completing ~10-minute shopping task |

6 STATISTICAL CONSIDERATIONS

General principles and analysis populations. We will use a two-sided critical alpha of 0.05 to conduct all statistical tests. All confidence intervals presented will be 95% and two-sided. Analyses of the primary, secondary, and other outcomes will include all randomized participants according to the trial arm they were randomized to receive. We will use complete case analysis to handle any missing data in analyses of the primary, secondary, and other outcomes.

6.1 Primary Endpoint

The primary outcome variable is the total number of calories from sugar-sweetened beverages the participant purchased during the shopping task (see also Table 2).

6.2 Secondary Endpoint

Secondary outcomes are listed in Table 2.

6.3 Statistical Methods

Data preparation and balance tests. To prepare the data, we will first examine all scales to ensure adequate internal consistency (i.e., Cronbach's alpha > 0.70), dropping items as needed to improve consistency. If we are unable to achieve adequate internal consistency by dropping items, we may exclude the unreliable scales from analyses (e.g., not analyze treatment effects on these outcomes).

Next, we will conduct balance tests. Specifically, we will report participants' age, gender, sexual orientation, Hispanic ethnicity, race, educational attainment, health literacy, household income, usual sugar-sweetened beverage consumption, and overweight status (body mass index [BMI] ≥ 25 kg/m²) by trial arm. We will summarize categorical variables as counts and percentages and continuous variables as means and standard deviations. The denominator for each percentage will be the number of participants within each treatment group, less any participants with missing data on the variable of interest. We will use *t*-tests and χ^2 tests to examine whether participants assigned to the trial arms differ on any continuous or categorical characteristics, respectively. We will report *p* values from these balance tests. Subsequent analyses will control for any unbalanced characteristics.

Analysis of the primary outcome (Efficacy analysis). We will use ordinary least squares regression (OLS) to examine whether the primary outcome differs by trial arm. Specifically, we will fit the following:

$$SSB \text{ calories purchased} = \beta_0 + \beta_1 \text{WARNING} + X\beta \quad (\text{Eq. 1})$$

Here, *SSB calories purchased* is the total calories from SSBs the participant had in her basket when she completed her shopping task, calculated as described in Table 2. WARNING is an indicator variable for whether the participant was in the health warning arm (WARNING = 1) or the control arm (WARNING = 0). We denote *X* as a vector of any participant characteristics (e.g., age, gender, race/ethnicity) found to be unbalanced across trial arms in balance tests.

The coefficient on WARNING (β_1) is the primary effect estimate, and gives the average difference in (adjusted) means between the treatment arm and the control arm. It is interpreted as the impact of SSB health warnings on total calories of SSBs purchased.

Planned exploratory analyses of the primary outcome. We will examine whether the following participant characteristics moderate (modify) the effect of SSB health warnings on SSB purchases:

- a) Age category (18-29, 30-39, 40-54, and 55 years or older);
- b) Sex (male vs. female);
- c) Sexual orientation (gay, lesbian, or bisexual vs. not);
- d) Race/ethnicity (white vs. non-white);
- e) Low educational attainment (some college or less vs. college or more),
- f) Limited health literacy (possibility or high likelihood of limited literacy vs. adequate literacy, based on score on the Newest Vital Sign^{63,64});
- g) Household income (\$50,000 or more vs. less than \$50,000);
- h) Usual SSB consumption (above vs. at or below the sample median);
- i) Overweight status ($BMI \geq 25 \text{ kg/m}^2$ vs. $BMI < 25 \text{ kg/m}^2$);

To test whether these characteristics moderate the effect of SSB health warnings on SSB purchases, we will fit a series of regressions (one for each potential moderator) taking the following general form:

$$SSB \text{ calories purchased} = \beta_0 + \beta_1 \text{WARNING} + \beta_2 \text{CHARACTERISTIC} + \beta_3 (\text{WARNING} * \text{CHARACTERISTIC}) + X\beta \quad (\text{Eq. 2})$$

Here, *SSB calories purchased*, *WARNING*, and *X* are as defined previously and *CHARACTERISTIC* is the moderator variable (e.g., an indicator for low educational attainment). Moderation is present if β_3 is statistically significant. We will probe significant interactions by calculating the marginal effect of health warnings on SSB calories purchased at different levels of the moderating variable.

Analysis of the secondary outcomes. We will use different analytic approaches to assess whether secondary outcomes differ by trial arm, depending on the level of measurement of the secondary outcome (i.e., continuous, count, or dichotomous).

The following secondary outcomes are continuous will be assessed using OLS regression:

- Number of calories purchased from all foods and beverages
- Mean intentions to limit consumption of beverages with added sugar
- Mean intentions to limit consumption of specific sugar-sweetened beverages
- Mean attention to trial labels

- Mean emotional reactions to trial labels
- Mean cognitive elaboration
- Social interactions about the labels
- Mean perceptions of added sugar content in specific sugar-sweetened beverages
- Mean attitudes toward consuming specific sugar-sweetened beverages
- Mean product attitudes toward specific sugar-sweetened beverages
- Mean outcome expectations regarding consumption of beverages with added sugar

These regressions will take the general form of:

$$Y = \beta_0 + \beta_1 \text{WARNING} + X\beta \quad (\text{Eq. 3})$$

Here, WARNING and X are as defined previously and Y is the continuous secondary outcome. As above, the effect estimates are given by the coefficient on WARNING (β_1). This coefficient gives the average difference in (adjusted) means between the treatment arm and the control arm; it is interpreted as the impact of SSB health warnings on the secondary outcome being examined.

One of the secondary outcomes, number of SSBs purchased, is a count variable (i.e., takes on only nonnegative integer values) and is thus better evaluated with a count data model. To examine number of SSBs purchased, we will begin by fitting a Poisson regression:

$$\text{Prob}(y|\lambda) = \frac{e^{-\lambda}\lambda^y}{y!} \quad \text{for } y=0,1,2 \quad (\text{Eq. 4})$$

where

$$\lambda = e^{(\beta_1 \text{WARNING} + X\beta)} \quad (\text{Eq. 5})$$

WARNING is an indicator for treatment arm, X is a vector of any unbalanced participant characteristics and y is the observed number of SSBs purchased. Following the advice of Kennedy,⁶⁵ we will use robust standard errors to address the potential for overdispersion. We will test model fit using the Pearson goodness-of-fit test;⁶⁶ if the null hypothesis of a Poisson distribution is rejected, we will use a negative binomial regression in place of a Poisson regression. In either case, we will report the average differential effect of being in the health warning arm (vs. being in the control arm) on the predicted number of SSBs purchased.

Finally, the following secondary outcomes are dichotomous and will be assessed using logistic regression:

- Purchase of a sugar-sweetened beverage
- Noticing of the trial labels

These regressions will take the general form of:

$$Prob(Y = 1|WARNING, X) = \frac{e^{(\beta_1 WARNING + X\beta)}}{1 + e^{(\beta_1 WARNING + X\beta)}} \quad (\text{Eq. 6})$$

WARNING and X are as defined previously, and Y is the dichotomous secondary outcome. For logistic regression results, we will report the average differential effect of being in the health warning arm (vs. being in the control arm) on the probability of the outcome occurring (i.e., probability the participant purchased a sugar-sweetened beverage), calculated using the method of recycled predictions.⁶⁶

Analysis of other outcomes. We will use OLS regression to examine differences by trial arm in the following other outcomes (all of which are continuously measured):

- Mean injunctive norms regarding consumption of beverages with added sugar
- Perceived message effectiveness of trial label
- Support for sugar-sweetened beverage health warning labels
- Mean self-efficacy to limit consumption of beverages with added sugar
- Mean response efficacy of limiting consumption of beverages with added sugar

To examine these outcomes, we will fit linear regressions of the general form:

$$Y = \beta_0 + \beta_1 WARNING + X\beta \quad (\text{Eq. 7})$$

WARNING and X are as defined previously and Y is the continuous other outcome. As above, the effect estimates are given by the coefficient on WARNING (β_1). This coefficient gives the average difference in (adjusted) means between the treatment arm and the control arm; it is interpreted as the impact of SSB health warnings on the outcome being examined.

Statistical software. Data preparation and analyses will be conducted in Stata Version 15.1 (StataCorp LLC, College Station TX).

6.4 Sample Size and Power

The primary objective of this trial is to evaluate the effect of SSB health warnings on total calories of SSBs purchased. We used G*Power3 to determine sample size needs for

addressing this objective.⁶⁷ At the time of sample size determination, no studies of SSB health warnings had examined behavioral outcomes. Thus, we drew on effect sizes from studies of warnings' impact on intentions to purchase SSBs. These studies report medium^{17,19} or large¹⁸ effect sizes. To account for the intention-behavior gap, we powered the trial to detect an effect size between small and medium (standardized Cohen's $f^2 = 0.02$, i.e., trial arm will explain 2% of the total variance in SSB purchases).⁶⁸⁻⁷⁰ Using these specifications and a two-sided alpha of 0.05, we determined a necessary sample of 395 to detect an effect of $f^2 = 0.02$ or larger with 80% power. To account for potential missing data or incomplete study visits, we aimed to enroll 400 participants (200 in each arm).

6.5 Interim Analysis

No interim analyses were planned.

7 STUDY INTERVENTION

The intervention is exposure to a textual sugar-sweetened beverage health warning label. The health warning label is a 1.5" octagon with red background, a white border, and white text, as described in Section 1.2 above. In the health warnings arm, SSB health warning labels are adhered directly to the front-of-package of all SSB containers in the mock store.

8 SAFETY MANAGEMENT

To ensure the safety of participants, the principal investigator will monitor all data, including answers to free response survey questions, throughout the data collection period. No adverse events or medical emergencies are anticipated, as participants are completing questionnaires and completing normal activities of daily living (selecting products at a small store). Further, given the very low-risk nature of the study, there were no *a priori* criteria for stopping the entire study prematurely due to safety concerns or unexpected adverse events. The PI will monitor for any adverse events or medical emergencies and promptly report these to the sponsoring IRB following standard reporting procedures.

9 DATA COLLECTION AND MANAGMENT

Participant confidentiality will be protected throughout all phases of the research, including data collection, analysis, and publication of results. Other than to schedule participants for their study visit (for which contact information must be collected), this study does not collect any identifying information. All data (responses to survey questions, product selections made during the experiment) will be de-identified (i.e., will only be attached to identification codes, and not to any identifiable information). The key linking identification codes and respondent information will be kept in a locked file cabinet in a locked office and on a secure, password-protected computer/server. The key will be destroyed after data collection is complete.

10 RECRUITMENT STRATEGY

This study aims to recruit a convenience sample of 400 adults through a variety of methods our team has used to recruit diverse samples,⁷¹ including via community subject pools at the University of North Carolina, Chapel Hill (UNC) and Duke University, printed flyers posted in campus and community venues and distributed in-person on UNC and Duke campuses, and online advertisements on sites such as Craigslist and Facebook. Individuals who are interested in learning more about the study are invited to complete an online screening questionnaire. The screening questionnaire assesses the prospective participant's age, usual SSB consumption (using the BEV-Q 15, a validated questionnaire⁵⁷), and own and parental educational attainment. Eligible participants are English-speaking adults at least 18 years old who consume at least 12 ounces of SSBs per week.⁵⁷ Eligible potential participants will be invited to schedule a time to participate. Ineligible participants will be thanked for their time.

11 CONSENT PROCESS

This study obtains informed consent separately for the pre-enrollment screening questionnaire (screening phase) and for the in-person study visit (intervention phase).

For screening questionnaire, this study obtains informed consent via an online consent form with electronic agreement. The online consent form is presented to participants before they begin the online screening questionnaire. Participants are asked to read the form and indicate whether they agree to participate in the research. If they agree to participate, they select a button

labeled “I consent” and proceed with the survey. If they do not agree, the survey is ended and no information is collected.

For the in-person study visit, this study obtains written informed consent. When participants arrive for their study visit, the experimenter (the PI or a trained research assistant) escorts them to a private study room in the lab suite. The participant is provided with a copy of the consent document. The experimenter reviews the consent document with the participant and answers any questions the participant has. The document the general nature of the study, the risks and benefits of the study, and the general procedures used. After reviewing the document with the experimenter and asking any questions she may have, the participant indicates whether she agrees to participate. If the participant agrees to participate, both she and the experimenter sign and date a copy of the consent document. If the participant declines to participate, she is thanked and the study visit is ended.

The consent form for the in-person study visit uses incomplete disclosure. Specifically, the consent document gives general information about the study purpose (i.e., “a study about how consumers make choices in a naturalistic store setting”) but does not provide enough detail to reveal the main study objective. Participants are given truthful information about the study procedures in general terms (i.e., that they will be asked to select items in a shopping task and to complete a survey about their experience the store, attitudes and beliefs, and personal characteristics), including truthful information about the risks and benefits of participating in the study, but are not be fully informed about the study’s expected findings. After completing the study visit, participants are provided with a “Debriefing” form that provides details about the nature and purpose of the study. They are also given the opportunity to ask any questions they have about the study.

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