Complete Title: Sugary Drink Labeling Study

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Protocol Synopsis

Study title	Sugary Drink Labeling Study
Funder	National Institute of Diabetes and Digestive and Kidney Diseases
Study rationale	• Sugary drinks are a top source of added sugar in the United States • "High in added sugar" warnings have been implemented in 10+ countries, but it is unclear whether these warnings would affect sugary drink purchasing in the US
Study objectives	• Evaluate whether a "High in added sugar" warning label reduces added sugar purchased from sugary drinks compared to a control label. • Evaluate whether a "High in added sugar" warning label changes other secondary outcomes compared to a control label.
Study design	Randomized clinical trial
Number of participants	~543 participants
Study duration	Each participant is in the trial for ~3 weeks. The trial enrollment period is expected to last ~24 months.
Study phases	The trial will have two phases: (1) Screening: screening for eligibility and obtaining consent, and (2) Intervention: intervention/experimental treatment

Study protocol

This study aims to determine whether new added sugar warnings on sugary drinks lead to a lower amount of added sugar purchased from sugary drinks. We aim to enroll approximately 543 adults ages 18 and older who have purchased at least one sugary drink from a store in the past week. Participants will attend 4 in-person study visits at our experimental store, spaced approximately 1 week apart. We will randomize participants to 1 of 2 trial arms at the time of scheduling. At the first visit, participants will provide written informed consent. At each study visit, participants will shop for beverages in the store and take a computer survey. Participants will view sugary drinks in the store labeled per their trial arm. Researchers will record in-store purchases, and other self-reported measures will be assessed via the computer surveys.

Statistical analysis plan

Predictions

For the primary outcome, we predict that the amount of added sugars purchased from sugary drinks will be lower in the added sugar warning arm compared to the control arm.

For secondary outcomes, we predict that the amount of total sugars purchased from all beverages, volume of sugary drinks consumed in the past 7 days, and perceived healthfulness of sugary drinks will be lower in the added sugar warning arm compared to the control arm. We predict that intentions to reduce sugary drink consumption, forgoing sugary drinks, learning something new, correct identification of beverages high in added sugar, and thinking about the harms of sugary drinks will be higher in the added sugar warning arm compared to the control arm.

Statistical methods

Analyses will be intent-to-treat, including all participants who attended Visit 1. Inferential tests will use a critical alpha of 0.05 or 95% confidence intervals and two-tailed tests.

We will descriptively present demographic characteristics separately for each trial arm. We will not conduct statistical balance tests that compare trial arms on demographic characteristics, following CONSORT guidelines for randomized clinical trials. For multi-item self-report measures completed by study participants, we will calculate the mean across individual items, assuming sufficient internal consistency reliability (Cronbach's alpha >=0.60). If internal consistency is lower, we will consider dropping items or analyzing individual items as separate constructs.

To examine the impact of trial arm on the primary outcome, we will use mixed-effects linear regression. The repeated measures outcome will be the amount of added sugars purchased from sugary drinks at each visit. The predictors will be trial arm (using the control arm as the reference group) and study visit (Visit 1, 2, 3, or 4). Analysis will treat the intercept as random.

We will explore whether the impact of trial arm on the primary outcome differs by the following potential moderator variables: prior exposure to warning labels, diagnosis of a chronic disease, having limited English proficiency, volume of sugary drinks consumed in the past 7 days at baseline, and income. For each moderator, we will repeat the analyses, adding the variable and the interaction of the variable with trial arm as predictors. If the interaction term is significant, we will report the impact of trial arm on the primary outcome at each level of the moderator. We will adjust p-values for probing moderation analyses for multiple post-hoc tests using a Bonferroni-Holm correction.

Next, we will examine the impact of trial arm on secondary outcomes. We will use mixed-effects linear and logistic regression for outcomes with repeated measures, using the same predictors as in the primary outcome model. For learning something new and correct identification of beverages high in added sugar (binary outcomes assessed only once), we will use standard logistic regression. For volume of sugary drinks consumed in the past 7 days (continuous outcome assessed only once), we will use standard linear regression.

Sample size needs

To estimate sample size needs for analyses of the primary trial outcome, we assumed 4 repeated measures, 2 trial arms of equal size, an intraclass correlation of .50, and 90% retention. An F-test for repeated measures was the statistical test chosen to compare the means of the 2 trial arms across 4 time points in G*Power. Alpha was set to .05 and power was set to .80. Based on previous studies examining the impact of labeling on behavior,[1,2] we aim to detect a small effect size (*d* =.20). The results of the power calculation indicated a total sample size of 543 participants.

References

1. Hall MG, Grummon AH, Higgins ICA, et al. The impact of pictorial health warnings on purchases of sugary drinks for children: A randomized controlled trial. *Plos Med*. 2022.
2. Grummon AH, Taillie LS, Golden SD, Hall MG, Ranney LM, Brewer NT. Sugar-sweetened beverage health warnings and purchases: A randomized controlled trial. *Am J Prev Med*. 2019;57(5):601-610.