

Online Store Experiment for Testing Non-Sugar Sweeteners Front-of-Package Label in Brazil

Hypotheses and Analytic Plan

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Hypotheses

The purpose of this study is to assess the impact of non-sugar sweeteners (NSS) front-of-package labels (FOPL) on Brazilian parents' food and beverage selections for their children. The study includes three arms: (1) a control group with no NSS FOPL, (2) a group exposed to a NSS FOPL modeled after the Mexican warning label for NSS, and (3) a group exposed to a NSS FOPL using the magnifying glass symbol currently implemented in Brazil for nutrients of public health concern. Participants will be instructed to select products for their child, including one yogurt, three beverages (for breakfast, lunch, and dinner), one granola, and one cereal bar. All products will display the FOPL for added sugars, sodium, and saturated fat as implemented in Brazil.

Primary Outcome

The primary outcome is the selection of products that do not contain NSS or added sugars, or that contain added sugars below the Brazilian FOPL threshold for added sugars (i.e., less than 10 g per 100 g) for granola and cereal bars.

We hypothesize that:

1. Compared to the control, the presence of a NSS FOPL, in addition to the FOPL for added sugar already implemented in Brazil, will increase the percentage of unsweetened/ low in sugar products selected.

Secondary Outcome

The secondary outcomes are the selection of products containing both NSS and are high in added sugars, defined as those displaying the Brazilian FOPL threshold for added sugars (i.e., more than 7.5 g per 100 ml for liquids, and more than 10 g per 100 g for foods).

We hypothesize that:

1. Compared to the control, the presence of a NSS FOPL will reduce the percentage of products selected that contain NSS.
2. Compared to the control and the NSS magnifying glass FOPL, the Mexico-based NSS FOPL will lead to the greatest reductions in the percentage of products selected that contain NSS.

STATISTICAL CONSIDERATIONS

Statistical Methods

The study is a randomized controlled trial testing the effects of two NSS FOPL systems on parents' food and beverage selections, compared with a no-NSS FOPL control. The effects of the two NSS FOPL systems on parents' food and beverage selections will also be compared with each other.

We will report unadjusted values for primary and secondary outcomes.

We will use a two-sided critical alpha of 0.05 to conduct all statistical tests. Primary analyses will be intent-to-treat, including all eligible participants with non-missing data for the outcome being analyzed.

The analysis will involve calculating the percentages of the selected products that are (1) unsweetened or not high in added sugars (for granola and protein bars), (2) high in added sugars, and (3) contain NSS, across the three study arms, overall and by food category.

To assess the impact of the experimental condition on product selection, we will run separate binary logistic regression models for the selection of products unsweetened or not high in added sugars (for granola and protein bars), products high in added sugars, and products containing NSS. The primary focus will be on

calculating predicted probabilities rather than reporting raw odds ratios, as predicted probabilities provide a more interpretable measure of the likelihood of selecting each product type across the study arms. We will use the margins command in Stata post-estimation to generate pairwise comparisons between the study arms. The independent variable will be group assignment (arm), and the model will be adjusted for relevant covariates if that differ significantly between arms.

We plan to conduct exploratory moderation analyses to examine whether the effects of a NSS FOPL vary based on sociodemographic and behavior characteristics such as age, gender, education, race, BMI, having diabetes and consumption of NSS. For all analyses, all pairwise comparisons of means will be examined for all outcomes. We will consider a result statistically significant at $p<0.05$.

Analyses will be performed with Stata/MP 18.0.

Sensitivity Analyses

We will describe dropout (defined as entering the store but not completing the purchasing task) by study arm. If differential dropout is identified, we will consider sensitivity analyses to handle missing outcome data, such as inverse probability weighting. We will compare the main effects to the primary results if warranted, based on the number of participants excluded from a moderation analysis due to missing demographic data.

Sample Size and Power

The planned sample size of 1,068 was determined to detect differences in the likelihood of selecting unsweetened products across study arms, based on effect sizes reported in a previous U.S. randomized trial of NSS FOPL in parents. Assuming $\alpha=0.05$, 80% power, and a standardized effect size of Cohen's $h=0.21$, we estimated that 356 participants per arm would be required and accordingly will enroll this number of participants in each of the three arms.

Eligible participants will be adults aged 20 years or older, living in Brazil, who are parents or guardians of children between 2 and 12 years old and who are primarily responsible for the household grocery shopping (more than 50%). Recruitment will occur nationwide through an online panel, with quotas for education, race, and geographic distribution to approximate the national profile. Individuals will be excluded if they are not a parent or guardian of a child aged 2–12 years, are younger than 20 years, are not primarily responsible for more than half of the household grocery shopping, are unable to read or understand Portuguese, or do not provide informed consent.

Outliers and Exclusions

We will examine detailed summary statistics on each continuous outcome and exclude observations with unrealistically high values (e.g., in the top 2% of values). We will also conduct sensitivity analyses excluding individuals who are in the lowest two percentiles of the expenditures, those who complete the study unusually quickly (e.g., based on the distribution of time to completion of ascertained during a soft launch of the study), and individuals who are non-compliant with the shopping instructions (<50% of products selected comply with the shopping list).