Testing "Ultraprocessed" Front-of-package Label Among Brazilian Consumers

Hypotheses and Analytic Plan

NCT #05842460

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Hypotheses

The goal of this study is to examine whether combined “ultraprocessed” and nutrient warning labels are more effective than nutrient warning labels alone at reducing purchase intentions of food and beverage products. Therefore, our primary hypothesis is that participants who see the combined “ultraprocessed” and nutrient warning labels will report a lower likelihood of purchasing the product than participants who see only nutrient warning labels (H1).

We will also examine the effect of combined “ultraprocessed” and nutrient warning labels on precursors to behavior change. Thus, we also hypothesize that, compared to nutrient warning labels alone, exposure to combined “ultraprocessed” and nutrient warning labels will lead to:

- Lower perceived product healthfulness (H2)
- Higher likelihood of identifying all products presented as ultraprocessed (H3)
- Higher perceived message effectiveness (H4)

Main Analyses

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

To prepare the data, we will average responses to each question across the four products presented to participants to create an average score on each continuous outcome for each participant. For the identification of ultraprocessed products outcome, we will create a new binary variable indicating whether each participant correctly identified all four products as ultraprocessed or not.

We will descriptively report unadjusted means and percentages for the primary and secondary outcomes. For continuous outcomes, we will verify that Cronbach’s alpha is sufficient (>0.7) and, if so, we will conduct t-tests for significance testing of our hypotheses. If Cronbach’s alpha is not sufficient (>0.7), we will instead use mixed models for significance testing allowing for variation by product type. For the dichotomous outcome, we will conduct chi-squared tests for significance testing.

Exploratory Analyses

We will examine whether participant characteristics (i.e. age, gender, educational attainment, and self-reported health status) moderate the effect of combined "ultraprocessed" and nutrient warning labels on the primary outcome, compared to nutrient warnings alone. We will also verify if understanding of the term "ultraprocessed," measured before the experiment, moderates the effect of the combined "ultraprocessed" and nutrient warning labels, compared to nutrient warnings alone.

For these moderation analyses, we will fit a series of linear regressions (one for each potential moderator) for the continuous outcomes and logistic regressions for the binary outcome. These models will include the trial arm, the moderator, and their interaction as predictors. We will probe significant interactions by calculating the marginal effect of health warnings on the outcomes at different levels of the moderating variables.

Sample Size and Power

This study will occur in a survey that will follow a parent experiment in a virtual grocery store. The total sample size was calculated based on the primary outcomes of this parent study. To avoid contamination, this study will only include participants who were assigned to the control arm in the parent study (~1,000 participants).

Using G*Power3.1, we determined the minimum effect size we would be able to detect with this pre-determined sample size. With a two-sided alpha of 0.05 and 80% power, we would be able to detect an effect of d=0.15 or larger. We determined that this sample size would be enough, given that, on a smaller preliminary study that we conducted using similar labels, we found an effect size of d=0.26 on thinking about the risks of eating the product and of d=0.22 on discouragement from wanting to buy the product.

Interim Analysis

No interim analyses are planned.