

Title: Ultraprocessed Foods in Colombia

NCT Number: NCT07528443

Study Protocol and Statistical Analysis Plan

Approval Date: 6/10/2026

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Protocol Synopsis

Study Title	Ultraprocessed Foods in Colombia
Funder	Bloomberg Philanthropies
Study rationale	<ul style="list-style-type: none">• Children's dietary practices are characterized by consumption of foods and beverages high in calories, sodium, sugars, and fats, when adopted early in life, shape taste preferences that persist into adulthood.• The frequent consumption of these products is strongly associated with overweight, obesity, and other non-communicable diseases.• Colombia has implemented policies such as front-of-package warning labels to signal when products have excess contain of sugar, sodium, saturated fats, trans fats and signal any presence of non-caloric sweeteners. However, Colombia does not restrict the marketing of these products.• The presence of playful colors, characters, celebrities, and influencers on packages could create a health halo effect.• This marketing exposure could reduce the expected impact of warning labels on vulnerable populations such as children.
Study objectives	Examine the impact of the presence of marketing characters and warning labels on behavioral intentions, risk perceptions and perceived message effectiveness, and whether the presence of characters weakens the impact of warning labels.
Study design	Between-participants randomized experiment.
Subject Population key criteria for and Exclusion:	Inclusion Criteria: <ul style="list-style-type: none">• Children and adolescents between 12 and 17 years old• Currently live in Colombia
Number of participants	~1944
Study duration	Each subject's participation will last approximately 15 minutes. The enrollment period is expected to last ~2 months.
Data and Safety Monitoring Plan	The principal investigator is responsible for data quality management and ongoing assessment of safety.

Study protocol

The study seeks to examine how marketing characters and warning labels on packaging affect purchase intentions among children aged 12 to 17 in Colombia and examine whether characters' presence weakens the warning labels' impact. This will be a 2x2 between-subjects experiment manipulating the presence or absence of characters and the presence or absence of warning labels. Participants will be randomly assigned to 1 of the 4 conditions [1. Warning label + Character, 2. Warning label, 3. Barcode control label+ Character, 4. Barcode control label] in an online survey programmed in Qualtrics.

Statistical Considerations

General Principles

We will use a two-sided critical alpha of 0.05 to conduct all statistical tests. We will use complete case analysis to handle any missing data in analyses of the primary and secondary outcomes. Regarding the models, all models will include robust standard errors to account for potential heteroscedasticity. In addition to p-values, we will report standardized effect sizes and 95% confidence intervals to facilitate interpretation.

Outcomes

Primary Outcomes

Hypothesis 1: Participants exposed to products with characters will report higher purchase intention and lower risk perception compared to participants exposed to products without characters.

Hypothesis 2: Participants exposed to products with warning labels will report lower purchase intention and higher risk perception compared to participants exposed to products with barcode control labels.

Hypothesis 3: The impact of warning labels on purchase intention and risk perception will be lower in the presence of characters.

Secondary Outcomes

Hypothesis 4: Participants exposed to products with warning labels will report higher perceived message effectiveness compared to participants exposed to products with barcode control labels.

Hypothesis 5: The impact of warning labels on perceived message effectiveness will be lower in the presence of characters.

Sample Size Needs

We powered the study for the smallest main effect we expected, the comparison between participants exposed to products with and without character conditions (Boyland, 2016). We assumed a small effect size of Cohen's $d = 0.12$ to be conservative in light of a similar study finding a slightly larger effect size, a critical alpha of .05, 3 repeated measures, a correlation among measures of 0.5, and 80% power using G*Power software. According to these parameters, the required sample size is approximately 472 per group, or a total of 1888 participants.

Analysis

The primary outcomes are purchase intention and risk perception. We will run a mixed effects linear regression model to account for the repeated measures across people. Analyses will examine the main effects of the characters vs. no characters and warning labels vs. barcodes, and their interaction in separate models for each outcome. First, we will run a mixed effects linear regression model purchase intention as the outcome and dummy-coded predictors of characters (yes or no) and warning labels (yes or no). This model will also include the interaction between warning labels and characters. We will repeat this modeling approach for the second primary outcome of risk perception.

The secondary outcome is perceived message effectiveness. We will use the same modeling approach as for the primary outcomes. For these analyses, we will average perceived message effectiveness across the different products to create one summary score for perceived message effectiveness, per person.

In sensitivity analyses to explore whether the pattern differs by product type, we will run and present separate stratified models for each outcome, one for each food category.

Lastly, we will explore whether the effects of warning labels on purchase intention vary according to individual or contextual factors, including gender, parental education, child's age, prior knowledge, social norms, and food consumption patterns. Each potential moderator will be tested by including an interaction term between warning labels and the moderator in separate multiple regression models.

Exclusions and Outliers

We do not expect any outliers on survey measures because the Likert-style response options are constrained.

References

Boyland, E. J., Nolan, S., Kelly, B., Tudur-Smith, C., Jones, A., Halford, J. C., & Robinson, E. (2016). Advertising as a cue to consume: a systematic review and meta-analysis of the effects of acute exposure to unhealthy food and nonalcoholic beverage advertising on intake in children and adults. *The American journal of clinical nutrition*, 103(2), 519–533. <https://doi.org/10.3945/ajcn.115.120022>