

**Testing Product Messages in Colombia**

**Study Protocol and Statistical Analysis Plan**

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PROTOCOL TITLE: Testing Product Messages in Colombia  
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I confirm that I have read this protocol and understand it.

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Date: 04/24/2023

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## PROTOCOL SYNOPSIS

<b>Study Title</b>	Testing Product Messages in Colombia
<b>Funder</b>	Bloomberg Philanthropies
<b>Study Rationale</b>	<p>According to the WHO, obesity and overweight are health conditions afflicting over a billion people worldwide. Obesity and overweight can lead to numerous health problems including cardiovascular disease, diabetes, musculoskeletal disorders, and various types of cancers (1). Colombia is not immune to this global health problem. In Colombia in 2016, more than half of adults were overweight and more than 22 percent of adults were obese (2). Additionally, obesity and overweight impact Colombian children. The Colombian Ministry of Health reports that approximately 18% of Colombian youth are overweight (3). As a result of this increasing health problem, the Colombian government has begun to take actions to address overweight and obesity in Colombia. The Colombian government (the Congress, the Ministry of Health) recently approved a law that would require warnings on the front of packages high in critical nutrients to inform consumers and reduce the intake of these unhealthy foods and beverages (4). Similar laws have been implemented in countries around the world, such as Chile, Peru, and Israel (5). Research is needed to inform the design of this law. The purpose of this study is to test the potential effectiveness of different labels to be used on the packaging of foods and drinks to promote healthy diets in Colombia. This research is time sensitive and politically relevant and will help to inform Colombian Ministry of Health as to how product labeling will help to dissuade consumption and inform Colombians of product healthfulness prior to the implementation.</p>
<b>Study Objective(s)</b>	<p>Primary</p> <ul style="list-style-type: none"><li>• To identify the impact of nutrient warnings on product selection and other outcomes compared to GDA labels, Nutriscore labels, and a no-label control, in Colombia.</li></ul> <p>Secondary</p> <ul style="list-style-type: none"><li>• To determine the effect of the nutrient warning label and the impact of the nutrient warning label on behavioral outcomes.</li></ul>
<b>Study Design</b>	Participants will electronically acknowledge their consent to participate in the study. The study platform (Qualtrics) will randomize participants to one of the four front-of-package label

	<p>conditions: nutrient warning, Nutri-Score, GDA, or a no-label control. The participants will complete a fruit-drink selection task, inquiring about healthfulness of fruit drinks with each designated front-of-package label. After completing the fruit-drink task, the participant will complete a single product assessment task. After these, the participants will answer objective understanding and perceived message effectiveness questions about a breakfast cereal. Finally, the participants will see one product with all three label types and select the most discouraging label. The study will end with standard demographic questions.</p>
<b>Subject Population</b> <b>key criteria for Inclusion and Exclusion:</b>	<p>Inclusion Criteria</p> <ol style="list-style-type: none"> <li>1. 18 years old or older</li> <li>2. Currently reside in Colombia</li> </ol> <p>Exclusion Criteria</p> <ol style="list-style-type: none"> <li>1. Participated in previous studies linked to this study</li> </ol>
<b>Number Of Subjects</b>	Approximately 8,000
<b>Study Duration</b>	<p>Each subject's participation will last approximately 15-20 minutes. The entire study is expected to last 1 month.</p>
<b>Study Phases</b>	<p>(1) Screening: screening for eligibility and obtaining consent</p> <p>(2) Randomization: Randomly assigning participants to one of four conditions</p> <p>(3) Survey: Direct participants to a Qualtrics survey measuring product selection and perceptions and reactions to front-of-package labels, as well as standard demographics.</p>
<b>Statistical Analysis Plan</b>	<p>We will descriptively report unadjusted means (and standard deviations) and percentages for the primary and secondary outcomes. We will use linear regression for continuous outcomes and logistic regression for dichotomous outcomes. We will conduct pairwise comparisons of the predicted means to examine differences by all label types. We will examine whether primary outcomes differ by education.</p>
<b>DATA AND SAFETY MONITORING PLAN</b>	<p>Researchers will store the study data on a remote terminal server, and only research investigators and staff will have access to the data.</p>

## BACKGROUND AND RATIONALE

### Introduction

According to the WHO, obesity and overweight are health conditions afflicting over a billion people worldwide. Obesity and overweight can lead to numerous health problems including cardiovascular disease, diabetes, musculoskeletal disorders, and various types of cancers (1). Colombia is not immune to this global health problem. In Colombia in 2016, more than half of adults were overweight and more than 22 percent of adults were obese (2). Additionally, obesity and overweight impact Colombian children. The Colombian Ministry of Health reports that approximately 18% of Colombian youth are overweight (3).

As a result of this increasing health problem, the Colombian government has begun to take actions to address overweight and obesity in Colombia. The Colombian government (the Congress, the Ministry of Health) passed a law in 2021 that would require nutrient warnings on the front of packages high in critical nutrients to inform consumers and reduce the intake of these unhealthy foods and beverages (4). Similar laws have been implemented in countries around the world, such as Chile, Peru, and Israel (5).

Research is needed to inform the design of this law. The purpose of this study is to test the potential effectiveness of different labels to be used on the packaging of foods and drinks to promote healthy diets in Colombia. This research is time sensitive and politically relevant and will help to inform Colombian Ministry of Health as to how product labeling will help to dissuade consumption and inform Colombians of product healthfulness prior to the implementation.

## STUDY OBJECTIVE

The purpose of this study is to determine what type of front-of-package label, whether a Nutri-Score label, nutrient warning label, or a guideline daily amount (GDA) label discourage purchases of “high in” fruit drink products for adult Colombian consumers.

### Primary Outcomes

- Selection of the less healthy fruit drink as the fruit drink the participant would rather buy.
- Correctly identifying which fruit drink was higher in sugar.

### Secondary Outcomes

- Perceived message effectiveness.
- Purchase likelihood of a product in the next week if it were available.
- Percentage of participants that correctly identify the less healthy product when selecting between two products.
- Percentage of participants who correctly identify that the product contains excess sugar, saturated fat, or sodium.
- Percentage of participants selecting each nutrient label as most discouraging them from consuming the product.

## INVESTIGATIONAL PLAN (brief overview)

### Study Design

The study design is a between-subjects randomized controlled trial. Qualtrics will randomly assign participants to one of four study arms in the Qualtrics survey. Participants will have an equal chance of being randomized to any of the trial arms.

### Study Arms:

1. Control Arm: no warning labels
2. Nutri-Score Label Arm: one label with a color-coded ranking A-E of the relative healthfulness of a product.
3. Nutrient Warning Label: one black, octagonal warning label with the text: “Exceso de [azúcares; grasas saturadas; or /sal/sodio]. Minsalud” followed by the text: “Evitar Su Alto Consumo”
4. Guideline Daily Amount Label Arm: five blue rectangular boxes including calories, total fat, saturated fat, sugar, and sodium given in kcal, g, respectively, and mg for sodium. Followed by the text: “De los valores diarios de referencia de nutrientes en una dieta de 2000 kcal.”



In Qualtrics, participants will be asked to complete three tasks. The products presented in each task will have a Nutri-Score label, nutrient label, GDA label, or no labels, depending on which arm the participant has been randomized to.

As the purpose of the study is to inform Colombia's front-of-package labeling policy, we set out to test front-of-package labels that have been implemented in other countries. Potential labeling options were determined through consultation with a food and health advocacy coalition in Colombia, who provided insight on which labels were most likely to be proposed as regulatory options in the Colombian legislature or Ministry of Health. As a result of these conversations, we decided to compare the GDA label (which the food industry has promoted), Nutri-Score label, and a no-label alternative to the nutrient warnings on specific outcomes related to identifying and discouraging selection of ultra-processed foods. We hypothesized that the nutrient warnings would perform best on all outcomes, as previous research has found nutrient warnings to perform best on such outcomes (6).

After completing drink/product selection task, participants will complete a Qualtrics survey measuring reactions to and perceptions of all three labels as well as standard demographics. Upon completion, participants will earn a pre-determined amount of points from Offerwise for completing the study. Participants are able to convert points into money once they accumulate a specified amount.

#### **Study Duration, Enrollment and Number of Subjects**

Participation in the study will last approximately 15-20 minutes. The entire study is expected to last one month.

#### **Study Population**

##### **Inclusion Criteria**

1. 18 years old or older
2. Currently reside in Colombia

##### **Exclusion Criteria**

1. Participation in previous studies linked to this study

## **STUDY PROCEDURES (what will be done)**

#### **Study Steps**

Participants will be recruited through Offerwise, a market research company with over 300,000 panel participants in Colombia. If interested, panel members will complete a screener in Qualtrics to see if they are eligible. If they are not eligible, panel members will be redirected to a termination page indicating they are not eligible to participate. If they are eligible, panel members will be redirected to a consent form. If they agree to the consent form, they will acknowledge their consent by clicking an arrow to proceed to the study.



Following online consent, Qualtrics will equally randomize participants to one of the four front-of-package label conditions: nutrient warning, Nutri-Score, GDA, or a no-label condition. On Qualtrics, participants will complete three tasks. They will be asked to complete a selection task, in which participants will be asked to select which fruit drink is higher in sugar, which they would rather buy, and which is most unhealthy. The fruit drinks will be displayed with the labels corresponding to the participant's randomly assigned label condition. We will only include selection tasks for one type of product due to survey space constraints. Following the selection tasks, the participant will be asked to complete a single product assessment task. They will view a prompt that reads: "The next questions are about food products. You will look at a few different products and answer questions about each one. Please keep in mind that this study seeks to evaluate your survey responses and not the sale of the product." Then, they will answer a series of questions about the yogurt, cookies, and sliced bread, which will show the participant's randomly assigned label condition. The participants will answer all questions about one product at a time (displayed in random order). After these, the participants will answer objective understanding and PME questions about the breakfast cereal. The breakfast cereal is always displayed last as the nutrient warning condition contains two labels. Finally, the participants will be randomly assigned to see the yogurt, cookies, or sliced bread again (one product only). However, this time, the product will not fashion a label. Instead, the three label types (nutrient warnings, GDA, and Nutri-Score) will be displayed underneath the product and the participant will be asked to select the most discouraging label. The study will end with standard demographic questions.

#### **Subject Completion/Withdrawal Procedures**

A study participant is determined to have completed the study when they have finished and exited the study survey. To withdraw their data from the study, a participant would have to contact the study team or the university IRB.

#### **Screen Failure Procedures**

Prior to entering into the study, individuals will complete a survey screener. If the individual is younger than 18 years old or does not live in Colombia, they will be deemed ineligible. Such participants will be redirected to a screen notifying them that they are ineligible for the study.

## **SCREENING AND MONITORING EVALUATIONS AND MEASUREMENTS** (how measurements will be made)

Measurements will include results from the selection and assessment tasks as well as subjective responses by participants. Secondary outcomes will include a variety of measurements, including perceived message effectiveness, 5-point Likert scale questions, and identification questions.

Question	Response Scale
<b>Primary outcomes</b>	
Which of these products would you rather buy?	1 = (image of control beverage) 2 = (image of experimental beverage)
Which of these products is higher in sugar?	1 = (image of control beverage) 2 = (image of experimental beverage)
<b>Secondary outcomes</b>	
How much does this label... <ul style="list-style-type: none"> <li>make you concerned about the health consequences of consuming this product?</li> <li>discourage you from wanting to eat consume this product?</li> <li>make consuming this product seem unpleasant to you?</li> </ul>	1 = Very much 2 = A lot 3 = A little 4 = Very little 5 = Not at all
How likely is it for you to want to purchase this product next week, if it were available?	1 =Very much 2 = A lot 3 = A little 4 = Very little 5 = Not at all
In your opinion, which of these products is <u>most</u> unhealthy?	1 = (image of control beverage) 2 = (image of experimental beverage)
Do you think this product has excess [saturated fat/sugar/sodium]?	1 = Yes 0 = No
Which of these labels would discourage you <u>most</u> from wanting to consume this product?	[answer choices are each of the label types randomly displayed]

## STATISTICAL ANALYSIS PLAN

### Hypotheses

#### *Primary Outcomes*

The overall purpose of this study is to identify the impact of nutrient warnings on product selection and other outcomes compared to GDA labels, Nutriscore labels, and a no-label control, in Colombia. The primary objectives of this study are to evaluate our hypotheses that, compared to GDA, Nutriscore, and control, a nutrient warning label will lead to:

1. Lower selection of the less healthy product in a set of two products as the product the consumer most wants to buy.
2. Better ability to correctly identify which product of a set of two has higher levels of sugar.

We will also explore whether the impact of the nutrient warning (vs. other study conditions) on these two primary outcomes differ by respondent's educational level.

### *Secondary Outcomes*

We hypothesize that the nutrient warning label (compared to other label types) will:

1. Have higher perceived message effectiveness.
2. Be the most discouraging label.

We hypothesize that the nutrient warning label (compared to all other conditions) – and all conditions compared to the control – will:

1. Increase the ability to correctly identify the most unhealthy product when compared with two options.
2. Increase the ability to correctly identify whether a single product contains excess sugar, saturated fat, or sodium.
3. Lower intentions of purchasing a product high in the nutrient of concern in the next week if it were available.

### **Statistical Methods**

We will use complete case analysis to handle any missing data. We will descriptively report unadjusted means (and standard deviations) and percentages for the primary and secondary outcomes.

We will use a two-sided critical alpha of 0.05 to conduct all statistical tests.

### **Sensitivity Analyses**

For PME, we will take the average of the 3 items for each product type if  $\alpha > .70$ . For all outcomes assessed between-subjects only, we will then assess whether the outcomes vary by study arm with regression models (linear for continuous outcomes and logistic for dichotomous outcomes).

For outcomes with multiple measurements per-person, we will fit mixed effects linear regression models for continuous outcomes (including PME) and a mixed effects logistic regression model for binary outcomes (including product selection, label selection, identification of healthier products), treating the intercept as random to account for repeated measures.

We will include indicator variables for warning message (between-subjects) and product type (within-subjects), as well as an interaction of warning message and product type. We will use postestimation commands to conduct pairwise comparisons of the predicted means to examine differences by all label types. We will correct for multiple comparisons. To evaluate the most discouraging label, we examine the proportion of participants that selected each warning label as the most discouraging and will conduct z-

tests to explore statistical significance of these differences. To assess whether the effect of the warning label on the primary outcomes differs by education, we will test for an interaction of warning label with low versus high education level (specified as dummy variables) and use a Wald chunk test to determine the joint interaction. We will use postestimation commands to predict means by warning label and education level and conduct pairwise comparisons of the predicted means.

### **Sample Size and Power**

Using an ANOVA model in G.Power. 3.1.9.4, we estimate that with a sample of ~8,000, alpha of 0.05, and 80% power, we can detect an effect of  $f=0.037$  for each of the primary outcomes between each arm and the control, which translates to an odds ratio of 1.14.

### **Outliers and Exclusions**

We will exclude participants from analysis if they are duplicate responders, complete the study in less than two minutes, or if they do not answer at least one primary or secondary outcome.

## **SAFETY MANAGEMENT**

Provided that this study is conducted completely online, and participants do not have any interactions with study staff there is no anticipation of adverse events. However, the investigators have provided an email to contact as well as the IRB contact information, on the consent form, should a participant be concerned about any aspects of the research study.

## **DATA COLLECTION AND MANAGMENT**

Researchers will store the study data on a remote terminal server, and only research investigators and staff will have access to the data.

## **RECRUITMENT STRATEGY**

Participants will be Offerwise participants who have voluntarily signed up to complete tasks remotely, including research surveys. Our study sample will include only those who self-enroll in the study based on interest, availability, and meeting the inclusion criteria. There is no specific advertisement for this study. Rather, Offerwise identifies users for the survey based on the inclusion criteria (age 18 or older and resides in Colombia) and informs them of the study opportunity.

## **CONSENT PROCESS**

To provide consent, individuals will first complete a survey screener in Qualtrics. If they are eligible for the study, they will be redirected to the study consent form. If the participant agrees to the consent form, they are informed that by continuing to the study, they are consenting to participate. The consent process is completed entirely online, and at no point in the study do participants interact with the study team.

## INFORMED CONSENT FORM

**Title:** Testing product messages for Colombia

**Instructions (Consent form):**

We would like to invite you to take part in a brief research study to better understand people's thoughts and perceptions about product messages. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. This survey is open to Colombian residents aged 18 and over.

You will complete a survey with questions about food product messages and your demographics.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty, at any time.

About 8,500 people will be in this research study. You will be in the study for about 15 to 20 minutes. This will be a one-time survey with no follow up expected. You will receive points through Offerwise for completion of this survey.

There are no direct risks or benefits to participating that we are aware of.

**Privacy and Confidentiality**

We will not collect any sensitive information from you. Your responses will be linked with a generated participant ID, which will not be identifiable. Note that the Offerwise platform is NOT meant to support participant anonymity, but your responses to this survey will remain confidential. Research personnel will keep data from this study on a password-protected computer server and your responses will not be identifiable.

Your Offerwise ID will only be collected for the purposes of distributing points and will not be associated with survey responses.

**Please only take this survey one time.**

If you have questions about the study, you can contact us at [cepreste@live.unc.edu](mailto:cepreste@live.unc.edu). If you have questions about your rights as a research subject, contact the UNC Institutional Review Board at 919-966-3113 or [IRB\\_subjects@unc.edu](mailto:IRB_subjects@unc.edu).

By clicking on the link to the study, you acknowledge that you have read the information above and agree to be in this research study. Thank you!

At the end of the survey, you will receive a code to receive credit for completing our study. Please enter your Qualtrics completion code in the box after you complete the survey so that you can receive your payment.

## PLANS FOR PUBLICATION

The investigators plan to publish as an open-access peer-reviewed paper. They will target public health peer-reviewed journals for manuscript submission.

## REFERENCES

1. "Obesity and Overweight." WHO, 3 March 2020. <https://www.who.int/en/news-room/fact-sheets/detail/obesity-and-overweight>. Accessed 6 March 2020.
2. Ritchie, Hannah & Roser, Max. "Obesity." <https://ourworldindata.org/obesity#what-share-of-adults-are-obese>. Accessed 6 March 2020.
3. Colombia, Ministry of Health. "Obesidad infantil: una amenaza silenciosa." Pamela Elizabeth Vallejo Figueroa, Iván Camilo, Sánchez Barrera, Jair Alberto Arciniegas Barrera, & Fabio Escobar Díaz, June 2019, <https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/PES/resumen-politica-obesidad-infantil-amenaza-silenciosa.pdf>.
4. El Congreso de Colombia. Ley No 2120. <http://www.andi.com.co/Uploads/LEY%202120%20DEL%2030%20DE%20JULIO%20DE%202021.pdf>. Published 2021. Accessed February 15, 2023.
5. Reyes, M., Garmendia, M.L., Olivares, S. et al. Development of the Chilean front-of-package food warning label. BMC Public Health 19, 906 (2019). <https://doi.org/10.1186/s12889-019-7118-1>.
6. Taillie, L.S., Hall, M.G., Popkin, B.M., Ng, S.W., Murukutla, N. Experimental studies of front-of-package nutrient warning labels on sugar-sweetened beverages and ultra-processed foods: A scoping review. Nutrients 12(2), 569 (2020). <https://doi.org/10.3390/nu12020569>.