Study Protocol and Analytic Plan

Title: Impact of Front-of-Package Labels on Weight Bias Among Latines
Date: April 29th 2024
NCT #: NCT06293937

Introduction

The goal of the analysis described in this document is to use data to be collected through an online experiment with a sample of Latine and low English proficiency adults to examine the effects on explicit weight bias of a selection task using 4 different types of front-of-package food labels. This document pre-specifies our planned analytic approach prior to data collection.

Study Protocol

Participants will complete an online randomized experiment programmed in Qualtrics. After providing informed consent, participants will be randomly assigned to view 1 of 4 types of front-of-package nutrient labels during a product selection task: numerical label, interpretive text-only label, interpretive label containing a magnifying glass icon, or separated interpretive labels containing a magnifying glass icon. Participants will first view their assigned label on 3 sets of products (with 3 products per set) and select the product they believe is most and least healthy and the product they most want to purchase. After this selection task, participants will answer questions measuring explicit weight bias and attribution of personal responsibility of body weight.

Hypotheses

Explicit weight bias (primary outcome): We hypothesize that there will be no difference in weight bias between participants in the 4 arms (H1).

Attribution of personal responsibility for body weight (secondary outcome): We hypothesize that there will be no difference in attribution of personal responsibility for body weight between participants in the 4 arms (H2).

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.

To prepare the data, we will verify that Cronbach's alpha for the explicit weight bias scale is sufficient (≥ 0.7) and, if so, we will average items to create a mean score on this scale for each participant. If Cronbach's alpha is not sufficient (<0.7), we will drop items as necessary to improve reliability or treat items as separate constructs. We will also examine the Spearman Brown coefficient for the two-item scale used to measure attribution of personal responsibility for body weight and create a mean score on this scale for each participant.

We will descriptively report unadjusted means for the primary and secondary outcomes for each experimental arm. To test H1 and H2, we will fit separate linear regression models including indicator variables for label type and specifying the numerical label as the referent type. We will additionally use these models to estimate the effects of text-only vs. magnifying glass, text-only vs. exclamation point, and magnifying glass vs. exclamation point. We will not adjust the p-value for each label type compared to the numerical label, but will adjust for multiple tests for the three additional pairwise comparisons using the Bonferroni-Holm correction.

Exploratory Analyses

We may examine how demographic characteristics (i.e., gender, age, race, education, English proficiency, percentage of life spent in the US, and perceived weight status) correlate to weight bias among participants. We will fit a linear model including these characteristics as independent variables. If the main analysis reveals a significant effect of the experimental arms on explicit weight bias, we will also include label type in the model as an independent variable.

Sample Size and Power

This study will follow a parent study examining the effects of a selection task using the aforementioned label types on participants' desire to purchase and ability to identify the healthiest product in each product set. The total sample size (~4,000 participants) was calculated based on the primary outcomes of the parent study.

Using G*Power3.1 (ANOVA: fixed effects, omnibus, one-way) we determined the minimum effect size we would be able to detect on our primary outcome with this pre-determined sample size. With 80% power, a critical alpha of 0.05, and 4 groups, we would be able to detect an effect of f=0.066 (equivalent to d=0.13). Given that a previous study to analyze the effect of FOPLs on weight bias obtained an effect size of d=0.16 comparing warning labels to control labels, this study's sample should be sufficiently large to detect similar effects.

Interim Analysis

No interim analyses are planned.

Exclusions and Outliers

We will exclude participants who complete the survey implausibly quickly (defined as <1/3 of the median completion time). We will exclude participants who complete less than 90% of the survey.