Complete Title: Impacts of Prolonged Exposure to Added Sugar Warning Labels on Explicit Weight Bias: a Randomized Controlled Trial

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NCT #: 07346001

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Study title	Impacts of prolonged exposure to added sugar warning labels on explicit weight bias: a randomized controlled trial
Funder	N/A
Study rationale	• Interventions are needed to address sugar-sweetened beverage (SSB) consumption, which is a top source of added sugar in the United States • Weight stigma is harmful and should be avoided in public health and nutrition interventions • "HIGH IN ADDED SUGAR" warnings have been implemented in 10+ countries to help address high SSB consumption, but it is unclear whether these warnings may impact weight stigma
Study objectives	• Evaluate whether "HIGH IN ADDED SUGAR" warning labels on SSBs impact explicit weight bias body weight attributional judgements • Evaluate whether the impact of "HIGH IN ADDED SUGAR" warning labels on explicit weight bias body weight attributional judgements varies by length of exposure to the warning labels • Evaluate whether the impact of "HIGH IN ADDED SUGAR" warning labels on explicit weight bias body weight attributional judgements varies by demographic characteristics
Study design	Randomized clinical trial
Number of participants	~543 participants
Study duration	Each participant is in the trial for ~3 weeks (for a total of 4 store visits spaced one week apart). The trial enrollment period is expected to last ~24 months.
Study phases	The trial will have two phases: (1) Screening: screening for eligibility and obtaining consent (2) Intervention: intervention/experimental treatment
Study arms and interventions	• Control label arm: the control label will display a neutral, square-shaped barcode; labels will be placed on the front of SSB containers in the experimental store • Added sugar warning arm: the added sugar warning will be octagon-shaped and will state "HIGH IN ADDED SUGAR"; warnings will be placed on the front of SSB containers in the experimental store
Primary outcomes	• Explicit weight bias, mean score: measured by survey (post shopping visit) through seven items. Items will present participants with pairs of antonyms and ask that they select the box between antonyms that they feel best describes their feelings and beliefs about people with obesity: (1) lazy - hard-working, (2) no will power - has will power, (3) good self - control - poor self-control, (4) active - inactive, (5) self-indulgent – self-sacrificing, (6) dislikes food - likes food, (7) undereats - overeats. Response options, which will be

presented as 5 boxes between antonyms, will be coded in a categorical 1-5 range, where higher scores represent higher endorsement of a stereotype that contributes to weight bias. Each participant's responses to each item will then be averaged across the seven items to obtain their final score on the outcome in a 1-5 range, where higher scores represent higher explicit weight bias.

- <u>Body weight attributional judgements, mean score</u>: measured by survey (post shopping visit) through two items. Items will ask participants how much they agree with two statements: (1) People with obesity are responsible for their weight; (2) People with obesity are to blame for their weight. Response options will be on a 5-point scale from strongly disagree to strongly agree, with higher scores representing higher agreement. Each participant's responses to each item will be averaged to obtain their final score on the outcome in a 1-5 range, where higher scores represent higher attribution of personal responsibility for body weight.

Statistical Analysis Plan

Hypotheses

We hypothesize that "HIGH IN ADDED SUGAR" warning labels will not lead to greater explicit weight bias and body weight attributional judgements.

Main Analyses

Analyses will include all participants who attended Visit 1. We will use complete case analysis to handle any missing data. Analyses will employ a critical alpha of 0.05 and two-tailed tests.

First, we will verify that outcomes exhibit sufficient internal reliability (Cronbach's alpha ≥0.7) and average responses across measure items. If internal reliability is not sufficient, we will drop items as needed to improve reliability or treat items as separate constructs.

To examine the impact of trial arm on each outcome, we will fit mixed-effects linear regression models, treating the intercept as random to account for repeated measures within participants. Models will regress each outcome on indicator variables for labeling condition (omitting the control arm as the reference), study visit (i.e., visit 1 or 4, omitting visit 1 as the reference), and the interaction between the indicator variables for the warning label arm and visit 4. If the interaction term is statistically significant, we will probe it and report the average differential effect (ADE) -i.e., differences in predicted means between study arms – of the warning label on the outcomes at each study visit. On the other hand, if the interaction term is not significant, we will drop it from the model and report the ADE the warning label on the outcomes across study visits.

Exploratory Analyses

We will examine whether participant characteristics (i.e., gender, age, race/ethnicity, and perceived weight status) and SSB purchase during the shopping task (yes/no) moderate the effect of the warning label on the primary outcome. If there are no significant interactions between labeling condition and study visit in the main analyses, we will fit a series of mixed-effects linear models

(one for each moderator) to regress each outcome on indicator variables for labeling condition, study visit, the moderator, and two-way interaction(s) between labeling condition and the moderator. If, alternatively, the main analyses reveal significant interactions between labeling condition and study visit, we will fit separate moderation models for visit 1 and visit 4. We will consider moderation to be supported if the interaction term(s) between labeling condition and the moderator (in either scenario) is/are statistically significant (for categorical moderators with more than 2 categories, we will use Wald tests to determine the joint statistical significance of the interactions post model estimation). If moderation is supported, we will probe the interaction(s) by calculating the marginal effect of the warning label on the outcome at different levels of the moderator.

Sample size needs

This study will occur in a survey that will follow a parent study in the experimental store, which will examine the impact of the "HIGH IN ADDED SUGAR" warning labels on SSB purchases. The total sample size (~543 participants) was calculated based on the primary outcomes of the parent study.

Using G*Power3.1.9.4 and specifying a between-subjects ANOVA (which should most closely approximate the first proposed mixed linear model), 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, two conditions, and two repeated measures, we would be able to detect an effect of $f=0.104$ (equivalent to **d=0.21**, considered a small effect) or larger for the "HIGH IN ADDED SUGAR" warning labels.

Interim Analysis

No interim analyses are planned.