Online Study of the Effects of Sugary Drink Warning Labels on Consumption

NCT05079477

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IRB Study Protocol and Analysis Plan

Protocol

Objectives

Overall objectives

The study objective is to determine to what degree sugar-sweetened beverages (SSB) warning labels increase consumers knowledge about the potential health harms of SSBs and reduce SSB intake. The study aims to assess the impact on purchasing behavior among adults of repeated exposure to SSB warning labels over time.

Background

Sugar-sweetened beverages (SSBs) significantly contribute to adult and childhood obesity: Nationally, two-thirds of adults and one-third of children are overweight or obese, with higher prevalence among Hispanics and blacks relative to whites (1,2). Excess weight is associated with numerous negative health, psychological, and economic consequences (3-9). No one food or beverage is solely responsible for obesity, but there are several reasons to target SSBs with policy interventions. Sugar-sweetened beverages are drinks with added caloric sweetener (e.g., soft drinks, fruit drinks, sports drinks, and flavored waters containing added sugars), and their consumption is strongly associated with obesity and obesity-related health problems, such as type 2 diabetes and cardiovascular disease (10-18). Intake of SSBs has increased dramatically in the last several decades, and they now represent the largest source of added sugar in the American diet (19,20,42). SSBs are consumed at least once per day by 51% of adults and 64% of youth (43). Although soda consumption has recently declined modestly (44), consumption of other SSBs like sports drinks has increased (19), and todays overall level of SSB consumption remains disturbingly high (19,43). Further, Black and Hispanic individuals consume more kilocalories (kcals) from SSBs compared to white individuals (19). For these reasons, it is important to study interventions to reduce SSB intake among racially and ethnically diverse adults and children.

Nutrition labeling widely used by policy makers, but label design affects degree of impact: Mandatory and voluntary front-of-pack or shelf-tag nutrition labeling systems have been implemented in over 20 countries (45). In the U.S., calories per bottle labels now appear on the front of most beverages (46) and chain restaurants soon must display kcal information on menus (47). Recently, legislative bills were introduced in California (21), New York State (22), Baltimore (23), and San Francisco (24) to require SSBs to display health warning labels on product containers and/or advertisements, much like tobacco warning labels. These warning labels are meant to educate consumers about the potential health harms of over-consuming SSBs and reduce consumption. A number of studies have shown that well-designed nutrition labels can influence behavior (48-58). Examples include: posters displaying SSB calories as minutes required to burn off the calories were associated with reductions in SSB corner store purchases among low-income adolescents (49). Traffic light labels have been associated with sustained decreases in unhealthy item sales and increases in healthy item sales in a hospital cafeteria (50). A randomized-controlled trial found that both traffic light and calorie labels encouraged 10% fewer calories purchased when employees ordered lunch ahead of time through an online portal (51). Supermarket studies have also found that front-of-package and shelf-tag labels influenced purchasing habits (52-58). Overall, food labels can influence behavior, but the design of the label matters.

Effects of tobacco warning labels on knowledge and behavior: The evidence to date suggests tobacco graphic warnings can impact smoking behavior (28-33). Studies across four countries observed significant increases in calls to national telephone helplines after contact information was displayed within health warnings (28-33) and Canada saw a 6% drop in adult smoking prevalence following implementation of graphic warning labels (but graphic labels were introduced along with other tobacco control measures, making it difficult to isolate the independent effect of labels) (34). Research also shows that labels influence beliefs and intentions (25,27,59-65). Smokers in Australia were more likely to think about quitting and avoiding cigarettes after the implementation of large pictorial warnings (59). Significant proportions of smokers surveyed in countries with health warning labels have reported that the labels have motivated them to quit and/or influenced their behavior (60-66). One-fifth of Canadian (65) and two-thirds of Australian (62) non-smoking youth reported that warnings helped prevent them from starting to smoke and approximately 90% of U.K. non-smoking youth reported that the warnings deterred them from smoking (61).

Mechanisms of label influence: Research shows that tobacco graphic warning labels are more impactful than text labels (59,64,67-78) and both are more impactful than no label (25-33). Pictorial warnings are more effective than text warnings at increasing message salience, awareness, perception of smoking risks, and smokers desire to quit as well as preventing non-smokers from imitating (59,64,66-78). Graphic labels may be more effective than text because they elicit greater emotional reactions. Negative emotional reactions have been associated with increases in thinking about risks, intentions to quit, and quitting behaviors (66,70,75,79). Research also found that warnings depicting shocking images (e.g., rotten teeth, throat, mouth, or lung cancer, gangrenous foot, sick baby in a hospital)

were rated as most effective and were more likely to be recalled by smokers (29,66,72,74-76,78,80-83). In addition, accompanying factual information written in a clear and direct manner increases message acceptance (66,72,76,84). While graphic labels with shocking images may be more effective than text-only labels, we decided to test sugar graphic warning labels which factually depict how much sugar is in each beverage. We are testing factual sugar graphic warning labels because they are more legally feasible than shocking images, capture attention, are easy to understand, and inform participants about the potential health risks of consuming added sugars. For these reasons, we hypothesize that sugar graphic warning labels will be more impactful than the calorie control condition.
Significant contributions of the proposed research: We expect this research to provide the first causal data on the influence of SSB warning labels relative to standard kcal labels on purchasing and consumption behaviors. These data are much needed as warning label policies have been proposed in two U.S. states and two cities with little empirical evidence. The proposed work will provide an evidence base on the effects of such labels to guide both scientific inquiry and policymaking.

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Study Design

Design

The primary objective of this study is to determine, before wide-scale implementation, to what degree SSB warning labels increase consumers knowledge about the potential health harms of SSBs and reduce SSB intake. This study will examine how repeated exposure to SSB warning labels influence adults' purchasing behaviors over time. Participants will be blindly randomized to 1 of 2 study conditions. Although participants will not know there are other conditions, it will be impossible to blind them to their own conditions as they will view the labels associated with their conditions.

Study duration

Participants will be randomized to 1 of 2 conditions and will buy snacks and beverages for four weeks via an online store. We anticipate it will take approximately one year to finish recruiting all subjects and for all subjects to complete the study. We will start recruiting subjects once IRB approval is obtained.

Characteristics of the Study Population

Target population

We will recruit 216 racially and ethnically diverse parents from Philadelphia and the surrounding communities. Participants will need to be at least 18 years old, a primary caregiver of a child between the ages of 6 and 11, able to read and speak English, be the primary grocery shopper for their household, have regular Internet access, live in the Philadelphia area (within Amazon Fresh delivery radius), must purchase SSBs at least once per month and report that the oldest of their children between 6 and 11 years old is consuming SSBs at least twelve times per month or

approximately three times a week. Additionally, participants must not have participated in the prior Warning Label Online Store study, or the Beverage Tax Evaluation study conducted by our research team.

Subjects enrolled by Penn Researchers
216

Subjects enrolled by Collaborating Researchers
0

Vulnerable Populations

Children Form
Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
Fetuses and/or Neonates Form
Prisoners Form
Other
x **None of the above populations are included in the research study**
The following documents are currently attached to this item:
There are no documents attached for this item.

Subject recruitment
We will advertise through Craigslist. We will also leverage the resources and community relationships of the UPENN CDC-funded PRC co-directed by Drs. Glanz and Volpp (Co-Is) who both have a long track record of successfully working with local communities on research partnerships. We will also utilize Facebook Advertising through a Facebook page created for the study in order to reach more potential participants throughout the Philadelphia community (Craigslist language and Facebook flyer attached to this submission). Following all guidelines related to the COVID-19 pandemic, we will also hand out flyers directly to consumers and post them in neighborhoods if it is safe to do so.

When individuals call in to inquire about the study, they will be asked a series of questions to determine if they are eligible for the study.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:
There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:
There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document
At the start of the study, participants will be given assigned money in the form of a store gift card to which researchers will add money throughout the course of the study. Participants will initially be given $15 to use to purchase items in the online store. Participants will be asked to purchase at least two items in the store each week (they must select at least one snack and one beverage). After purchasing at least two items during the first week, a participant's account will increase by $15 the following week as an incentive to remain in the study. For weeks three and four, participants will receive an additional $17 in their account to purchase more products in the store. Whatever money they do not spend in the online store will accrue over time and at the end of the study, they will be mailed a physical ClinCard (debit card) that will be loaded with the value of the unspent money as well as an additional $20 for completing the final survey. The total compensation for full participation is $84 per participant.

Study Procedures

Suicidal Ideation and Behavior

Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures

To conceal the study's purpose, participants will be told that we are conducting consumer market research to learn about their experiencing shopping in an online snack store. Participants will be recruited on the phone. During this initial phone call, consent will be obtained and documented by the research assistant in REDCap, and participants will be given a tutorial about shopping in the online store. After the recruitment call, participants will be texted or emailed a link to a survey asking them to provide demographic information and beverage consumption information in a REDCap survey. They will also be mailed a welcome packet which includes a copy of the informed consent form, a Welcome Letter that gives them an overview of what they will be asked to do as well as answers to any frequently asked questions, in addition to an Online Store Guide to help participants navigate our online store interface (all attached to this submission).

After consent is obtained, participants will be randomized to one of 2 label conditions in REDCap: 1) calorie labels (control); or 2) sugar graphic warning labels. Afterwards, participants will be emailed a web-link and password that will direct them to the store interface based on their label condition. Participants will be asked to shop in the store for a total of four weeks. For the first two weeks, participants will receive $15 in their online store account. For weeks three and four, participants will receive $17 in their online store account. For all of the weeks, participants will be asked to purchase at least one beverage and one snack from the online store. Each week participants will receive up to 3 text reminders to shop in the online store. If participants are non-responsive via text, we will send 3 email reminders, and then 3 phone calls. Twice a day (excluding weekends) an RA will process and purchase the orders through our Amazon.com Prime account, which will enable us to ship the actual purchases within a few days. If for some reason Amazon Fresh does not have a product in stock, we will send the participant a replacement item. At the end of four weeks, research assistants will email or text participants with a REDCap link to a final survey for them to complete. After participants complete the final survey, a debriefing and consent form will appear on their screen. After participants read the debriefing statement, they will have the choice of either withdrawing from the study or indicating that it is still okay for the researchers to use their data (see attached). Participants will be required to answer this last question of consent before the survey can be considered completed.

Upon study completion, participants will be mailed a final study packet which includes the following: 1) Study Conclusion Letter (thanks them for their participation and gives a brief overview of the next steps to activate their study debit card in the form of a ClinCard which we will use to pay them for their participation), 2) Study ClinCard and ClinCard FAQ (details information on how to use a ClinCard), 3) Final Debrief Information Sheet (paper copy of the debriefing form that they saw on the Final Survey). All forms are attached to this submission.

The following documents are currently attached to this item:
There are no documents attached for this item.

Deception

Does your project use deception?
Yes

A. Deception/incomplete disclosure is typically only acceptable in studies with no more than minimal risk. Please detail why this study is minimal risk.
This study poses minimal risks. Participants will answer questions over the phone with a research participant, shop in a Shopify store, and complete self-report surveys via REDCap. No protected health information will be collected.

B. The deception/incomplete disclosure should have no adverse effects on welfare. Please outline how all adverse effects are minimized.
One potential risk is breach of confidentiality. We will minimize these risks by assigning a random participant identification number and stripping all identifying information from the dataset at the end of the study. All study data will be stored in REDCap and the PEACH Lab secure drive. Only the researchers involved in this study and those responsible

for research oversight will have access to the identifiable information provided. Any de-identified data shared will be done so via PennBox, a secure method to transfer files.

C. The IRB must determine that the value of the study is sufficient to warrant waiving some aspects of the requirement for full disclosure in the informed consent process. Please outline the scientific validity for using deception in this instance.
There is some information about the study that we will not initially share with participants. It will be necessary to omit certain details on the first day of the study so that we can create a realistic situation that will allow participants to react genuinely and spontaneously without second-guessing their intuitive choices. To conceal the study's purpose, participants will be told that we are conducting consumer market research about online shopping experiences and behaviors. We will explain that the online interface they are using may change throughout the study.

D. There is no alternative to address the scientific question in a valid manner but to use deception/incomplete disclosure. Other effective, non-deceptive approaches are not feasible. Please detail why alternatives are not feasible.
There is some information about the study that we will not initially share with participants. It will be necessary to omit certain details on the first day of the study so that we can create a realistic situation that will allow participants to react genuinely and spontaneously without second-guessing their intuitive choices. To conceal the study's purpose, participants will be told that we are conducting consumer market research about online shopping experiences and behaviors. We will explain that the online interface they are using may change throughout the study.

E. Debriefing is done, when appropriate, and the deception/incomplete disclosure is explained to the participant before the end of participation in the research. Please detail if you are debriefing participants, and if not, why not.
All participants will be debriefed at the end of the study to inform them about the true study purpose. At the end of four weeks, research assistants will text or email participants with a REDCap link to a final survey for them to complete. After participants complete the final survey, a debriefing and consent form will appear on their screen. After participants read the debriefing statement, they will have the choice of either withdrawing from the study or indicating that it is still ok for the researchers to use their data. Participants will be required to answer the last question before the survey can be considered completed.

F. When appropriate, subjects could be informed prospectively of the use of deception/incomplete disclosure and consent to its use: see the suggested consent language: *"In some research studies, the investigators cannot tell you exactly what the study is about before you participate in the study. We will describe the tasks in the study in a general way, but we can't explain the real purpose of the study until after you complete these tasks. When you are done, we will explain why we are doing this study, what we are looking at, and any other information you should know about this study. You will also be able to ask any questions you might have about the study's purpose and the tasks you did. Though we may not be able to explain the real purpose of the study until after you complete the tasks, there are no additional risks to those that have been described in this consent form."*
There is some information about the study that we will not initially share with participants. It will be necessary to omit certain details on the first day of the study so that we can create a realistic situation that will allow participants to react genuinely and spontaneously without second-guessing their intuitive choices. To conceal the study's purpose, participants will be told that we are conducting consumer market research about online shopping experiences and behaviors. We will explain that the online interface they are using may change throughout the study.

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
We will use a generalized estimating equation (GEE) modeling approach. Specifically, a linear GEE model of the transformed outcome (log10 (calories +1)) will be fit to a model with 1 categorical variable as the independent variable indicating the experimental condition (e.g., control is the reference) and an indicator for the corresponding measurement time (1, 2, 3, or 4 weeks). Such a model will allow us to examine overall treatment and time effects. Inferences will be adjusted appropriately to control the Type 1 error rate for multiple comparisons (e.g., Bonferroni).