Complete Title: Consumer Responses to Alcohol Warnings
Short Title: Consumer Responses to Alcohol Warnings
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Protocol Synopsis

Study Title	Consumer Responses to Alcohol Warnings
Funder	NA
Clinical Phase	NA
Study Rationale	• Policymakers and public health organizations are increasingly interested in communicating alcohol's harms to the public, including through mandated warning labels as well as mass media campaigns. • Communicating alcohol's harms could increase consumer understanding of these harms and reduce alcohol consumption and alcohol-related health harms. • Alcohol contributes to more than 200 health harms, giving policymakers and public health organizations many options to choose from when selecting topics to include in messages about alcohol-related harms. • However, it remains unknown which of these topics should be prioritized in communication efforts.
Study Objective(s)	Primary • To evaluate whether alcohol warnings about different topics elicit higher perceived message effectiveness than control messages. Secondary • To evaluate whether alcohol warnings about different topics elicit higher reactance than control messages.
Study Design	Randomized experiment.
Subject Population key criteria for Inclusion and Exclusion:	Inclusion Criteria 1. Age 21 and older 2. Reside in the United States 3. Able to complete a survey in English Exclusion Criteria 1. Under the age of 21 2. Reside outside of the United States 3. Unable to complete a survey in English
Number of Subjects	2,500
Study Duration	Each subject's participation will last approximately 10 minutes. The enrollment period is expected to last ~1-2 weeks.

Study Phases	There are two phases: (1) Screening: screening for eligibility and obtaining consent and (2) Intervention: study intervention/experimental treatment.
Efficacy Evaluations	The primary outcome is perceived message effectiveness for discouraging alcohol consumption. It is measured with 1 item adapted from prior studies.
Statistical and Analytic Plan	Primary outcome • We will use linear mixed models to examine the effect of each alcohol warning topic on perceived message effectiveness compared to control topics. Secondary outcomes • We will use linear mixed models to examine the effect of each alcohol warning topic on message reactance compared to control topics.
Data and Safety Monitoring Plan	• The principal investigator is responsible for data quality management and ongoing assessment of safety.

Introduction

The goal of the analysis described here is to use data we collected through an online randomized experiment to examine consumer responses to alcohol warning messages about different topics. This analysis examines the effects of warning topic (e.g., mouth cancer, liver damage) on perceived message effectiveness (primary outcome) and message reactance (secondary outcome).

This analysis plan pre-specifies the analyses before collecting data and therefore serves as our ex-ante planned analysis.

Study Protocol

Participants will complete an online randomized experiment programmed in Qualtrics. After providing informed consent, participants will view and rate messages on perceived message effectiveness (primary outcome) and message reactance (secondary outcome). Participants will be randomly assigned to 1 of 4 topic sets. Each topic set includes messages about 6 different topics: 5 warning topics and 1 control topic. (The warning topics vary across topic sets, but the control topic is the same across all topic sets). Participants will view messages about these topics in random order. Participants will view and rate 2 messages per topic (shown in random order within topic), for a total of 12 messages.

Statistical Considerations

General Principles

We will use a two-sided critical alpha of 0.05 to conduct all statistical tests. All confidence intervals presented will be 95% and two-sided. Analyses of the primary and secondary outcomes will include all randomized participants according to experimental conditions they were randomized to (i.e., intent-to-treat). We will use complete case analysis to handle any missing data in analyses of the primary and secondary outcomes.

Primary Outcome

The primary outcome is perceived message effectiveness for discouraging alcohol consumption. We will measure perceived message effectiveness with 1 item adapted from prior studies: "How much does this message discourage you from wanting to drink alcohol?" Response options will range from not at all (1) to a great deal (5).

Hypothesis 1. We hypothesize that all alcohol warning topics receive higher perceived message effectiveness ratings than the control topic.

Secondary Outcome

The secondary outcome is message reactance. We will measure message reactance with 1 item adapted from prior studies: "This message exaggerates the health effects of alcohol." Response options will range from strongly disagree (1) to strongly agree (5).

Hypothesis 2. We hypothesize that that all alcohol warning topics receive higher message reactance ratings than the control topic.

Statistical Methods

1. Analyses of the primary outcome:
    a. We will use linear mixed models to **evaluate the effect of each alcohol warning topic compared to the control topic on the primary outcome of perceived message effectiveness.** We will regress perceived message effectiveness on a set of indicator variables representing each alcohol warning topic (e.g., mouth cancer, throat cancer, breast cancer, etc.), excluding the control topic as the referent. We will treat the intercept as random to account for repeated measures within participants. The coefficients on the alcohol warning topics give the average difference in mean perceived message effectiveness between each warning topic and the control topic. Hypothesis 1 will be supported if all coefficients on the alcohol warning topics are positive and statistically significant. Given the exploratory nature of the study, we do not plan to adjust p-values for multiple comparisons.
    b. In addition to testing Hypothesis 1, we will also **descriptively rank the alcohol warning *topics*** on the primary outcome of perceived message effectiveness. We will estimate mean perceived message effectiveness for each alcohol warning topic (averaging across messages for each topic) and rank those means.
    c. Finally, we will **descriptively rank the alcohol warning *messages*** on the primary outcome of perceived message effectiveness. We will estimate means for each alcohol warning message and rank those means.
2. Analyses of the secondary outcome:
    a. We will use linear mixed models to **evaluate the effect of each alcohol warning topic compared to the control topic on the secondary outcome of message reactance**. We will use the same approach as for the primary outcome (see no. 1 above).
    b. We will **descriptively rank the alcohol warning *topics*** on the secondary outcome of message reactance. We will estimate mean reactance for each alcohol warning topic (averaging across messages for each topic) and rank those means.
    c. We will **descriptively rank the alcohol warning *messages*** on the secondary outcome of message reactance. We will estimate mean reactance for each alcohol warning message and rank those means.

We do not plan to conduct moderation analyses.

Sample Size and Power

We plan to collect data from ~2,500 participants (~625 per topic set). We used G*Power to estimate sample size needs.[1] We estimated power to detect an effect of each warning topic vs. the control topic assuming an alpha=0.05 and correlation among repeated measures of 0.6 (based on a prior study of alcohol warnings[2]). We estimated power assuming 2 repeated measures, reflecting that our contrast of interest has two within-subjects levels (warning topic vs. control).

Under these assumptions, our sample size will yield 80% power to detect a small standardized effect of Cohen's *f*=.05 (or Cohen's *d*=.10) or larger of each warning topic vs. the control topic. A prior study of alcohol warning topics found effects of this size or larger when comparing perceived message effectiveness of alcohol warning topics vs. control topics.[2]

Exclusions and Outliers

We will exclude participants who do not complete the survey or who complete the survey implausibly quickly (defined as <1/3 of the median completion time).

References

1. Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*. 2007;39(2):175-191. doi:10.3758/BF03193146

2. Grummon AH, Ruggles PR, Greenfield TK, Hall MG. Designing effective alcohol warnings: Consumer reactions to icons and health topics. *Am J Prev Med*. Published online 2022. doi:https://doi.org/10.1016/j.amepre.2022.09.006