Study Protocol

Title of Project: Evaluations of Alcohol Warning Labels
NCT #: NCT06129487
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1. Study Synopsis

Title/Acronym: Evaluations of Alcohol Warning Labels
Funding Source(s): NIH
Investigational Intervention(s) and/or Product(s): Different types of alcohol warning labels
Purpose: To test the effectiveness of alcohol warning labels to communicate the cancer risk of alcohol
Objectives: To examine alcohol consumers' reactions to alcohol warning labels that feature narrative or non-narrative content
Design/Methodology: Randomized experiment
Outcome Measures: Affective and cognitive responses toward alcohol warning labels, beliefs, attitudes, intentions, and behaviors related to alcohol
Study Population: U.S. adult (21+) moderate and heavy drinkers
Study Duration: 1 minute for the screening survey; 15 minutes for the main experiment; 5 minutes for the follow-up survey.
Settings/Locations: Surveys will be conducted online

2. Rationale/Significance

Alcohol use is a major preventable risk factor for cancer in the United States, but few Americans are aware of the risk (R. Ma & Ma, 2022). A promising approach to raising awareness of risk is to include pictorial warning labels (PWLs) on alcohol-containing products, but there is a limited understanding of the design and impact of such warnings (Clarke et al., 2021; Z. Ma, 2022). The proposed project is relevant to public health because determining the effectiveness of pictorial warning labels that feature narrative content to communicate cancer risk can raise awareness and potentially reduce harm.

3. Purpose and Objectives

3.1. Purpose

The proposed project aims to evaluate the impact of narrative (vs. non-narrative) PWLs on visual attention, message reactance, risk perceptions, and intentions to reduce and stop drinking.

3.2. Objectives

Specific Aim 1: Determine the effect of narrative PWLs on visual attention and message reactance.

Specific Aim 2: Determine the effect of narrative PWLs on risk perceptions and intentions.

3.3. Hypotheses/Research Questions

H1: We hypothesize that narrative PWLs will lead to greater visual attention and less message reactance than non-narrative PWLs.

H2: We hypothesize that narrative PWLs will lead to higher risk perceptions and higher intentions to reduce and stop drinking than non-narrative PWLs.

4. Study Design

To examine the effect of narrative and non-narrative PWLs on visual attention, reactance, risk perceptions, and behavioral intentions, we will employ an online randomized experiment through the Qualtrics survey platform, which can be configured to redirect participants to Sticky by Tobii, a webcam-based eye-tracking platform. We plan to recruit adult moderate and heavy alcohol users via Prolific, a research company that provides online study panels. Participants will first be invited to participate in an online screening survey. Eligible participants will be invited to participate in the main experiment. In the main experiment, participants will first answer questions concerning baseline alcohol consumption and other background information. Then they will engage with a webcam-based eye-tracking task through Sticky by Tobii. Participants will first read instructions and tips related to completing the eye-tracking task. They will complete a brief calibration procedure and be presented with either three narrative PWLs or three non-narrative PWLs. Sticky by Tobii will record participants' gaze, thereby measuring visual attention to each PWL. After viewing each PWL, participants will answer a few questions. After viewing all three PWLs, they will answer questions based on all images combined. Upon study completion, participants will be compensated. A follow-up survey will be sent to participants after two weeks, which includes questions about their drinking behaviors and risk perceptions.

5. Analytical Plan

We will analyze the data using the statistical software SPSS. First, we will use descriptive statistics to provide study sample characteristics. Then, we will conduct independent-samples *t*-tests and chi-square tests to check whether there are differences in background variables (i.e., demographic characteristics and baseline alcohol consumption) between conditions. If there are a significant association between the experimental condition and a specific background variable(s), we will control for this variable(s) in all analyses. To test the first hypothesis, we will conduct multilevel mixed-effects linear regressions to examine the effect of narrative (vs. non-narrative) PWLs time until noticed, time viewed, and number of visits, and reactance. We will also control for repeated measures because each participant will view three PWLs that vary in cancer type within their assigned

condition. We will check the assumptions of these analyses. To test the second hypothesis, we will conduct independent-samples t-tests to examine the effect of PWLs type (narrative vs. non-narrative) on risk perceptions and behavioral intentions when there are no differences in the distribution of background variables between conditions. If there are differences in the distribution, we will conduct a series of analyses of covariance (ANCOVA). Assumptions of these analyses will be checked.

6. Study Participants

6.1. Study Population

Participants will be recruited through the Prolific panel. Participants must meet both criteria for eligibility: (1) be at least 21 years old; (2) have consumed more than three alcoholic drinks per week over the past year, which is to ensure they are current moderate or heavy drinkers defined by the Centers for Disease Control and Prevention (2018); and (3) be willing to participate in remote eye tracking tasks and have necessary technical support to complete remote eye tracking tasks (i.e., having access to high-speed Internet and a computer/tablet/phone equipped with a high-speed camera). We will carry out the initial screening over an online survey.

6.2. Number of Participants

Number of people expected to be screened: 3,000

Number of people expected to be enrolled: 800.

6.2.1. Sample Size

No previously published work has examined the effect of narrative (vs. non-narrative) PWLs on visual attention and reactance. In our preliminary work, we conducted an online experiment testing the effect of PWLs type among adult moderate and heavy drinkers. We found that participants who saw non-narrative PWLs reported significantly higher reactance to the warnings than those who saw narrative PWLs (r = .19). Therefore, in the proposed project, we will use the effect size of r = .19 to estimate the sample size. With the alpha level set at .05, we will need 213 participants to achieve a statistical power of .80. The final sample size needs to account for possible failure to (1) complete the eye-tracking task and (2) generate usable eye-tracking data for those who complete the task. Based on a recent remote eye-tracking study (Chen-Sankey et al., 2023) and information provided by the Sticky by Tobii team, we plan to screen 1,200 participants (41% rate of completion) and enroll 500 participants (43% rate of usable data).

Because risk perceptions and behavior intentions are also our primary outcomes, we conducted an additional power analysis to calculate the sample size for these two

outcomes. Based on previous research (e.g., Oschatz & Marker, 2020), narratives had a small effect on persuasion. With the alpha level set at .05, we would need at least 800 participants to detect an effect of d = .20 with 80% power in an independent t-test.

Given that the sample size to detect a significant effect on risk perceptions and behavior intentions (N=800) is larger than that on reactance (N=500), we decided to enroll 800 participants in our main experiment. Accordingly, we would need to screen 1,951 participants (41% rate of completion).

Running the study resulted in 1,045 eligible participants from 1,922 screened participants. Of the 1,045 eligible participants, only 404 participants so far completed the main experiment successfully. Increasing the screener eligibility to 3,000 is expected to increase the successful completion of the main study to the projected 800.

6.3. Eligibility

Inclusion criteria: (1) be at least 21 years old; (2) have consumed more than three alcoholic drinks per week over the past year; and (3) be willing to participate in remote eye tracking tasks and have necessary technical support to complete remote eye tracking tasks (i.e., having access to high-speed Internet and a computer/tablet/phone equipped with a high-speed camera).

Exclusion criteria: (1) be younger than 21 years old; (2) has not consumed more than three alcoholic drinks per week over the past year; and (3) be not willing to participate in remote eye tracking tasks and have necessary technical support to complete remote eye tracking tasks (i.e., having access to high-speed Internet and a computer/tablet/phone equipped with a high-speed camera).

We will use a short online screening survey to determine eligibility. A copy of the screening survey is included in the submission. The screening data will not be retained about individuals who are not enrolled in the research. The screening data will only include their Prolific ID, but not other types of identifiers.

6.4. Vulnerable Populations

This study will not enroll vulnerable populations.

6.5. Recruitment Procedures

We will recruit adult moderate and heavy alcohol users via Prolific, which is an online platform to recruit participants. The screening data will not be retained about individuals who are not enrolled in the research. The PI, Dr. Zexin Ma, will set up the study on Prolific. Participants can send a message to the PI using the built-in messaging system on Prolific. When applicable, the PI will also provide her email address to participants: zexin.ma@uconn.edu

A copy of recruitment materials is included in the submission.

6.6. Consent/Assent Procedures

After eligible participants sign up for the study, they will be provided with a link to the online experiment. At the beginning of the study, participants will be asked to read the consent form and click the 'I accept' button to proceed. To ensure participants can understand the consent, the information will be written at no higher than an eighth-grade reading level. Participants will also be informed that their decision to participate in this study is voluntary. They can choose to stop their participation at any time or skip any part of the study if they are not comfortable.

A copy of the consent form is included in the submission.

6.7. Costs/Reimbursement

This study will be conducted online, so there will no costs incurred by subjects as a result of participation.

6.8. Compensation/Incentives

Study	Payment per participant	Payment schedule	Rationales
Screening survey	$0.2	After study completed	$12 per hour, as recommended by Prolific
Main experiment (completed)	$3	After study completed	$12 per hour, as recommended by Prolific
Main experiment partial payment	$0.2	After participants return their submission	$12 per hour, as recommended by Prolific
Follow-up survey	$1	After study completed	$12 per hour, as recommended by Prolific

Note: Prolific charges 25% of service fee for each study.

6.9. Withdrawal/Termination

Participants can choose to stop their participation at any time. Because this research project consists of three parts: the screening survey, the main experiment, and the follow-up survey. In the event participants withdrawal after completing one part, their data for the completed part will be kept. For example, a participant completes the main experiment but not the follow-up survey, their data in the main experiment will be kept.

Note that Sticky by Tobii (the webcam-based eye-tracking) will report a "terminated" category from those that begin the eye-tracking portion of the study. These include participants that terminate their participation voluntarily (e.g., close the browser) and encounter technical failures (e.g., cannot calibrate). If a participant is terminated by the eye-tracking platform, they will not be allowed to complete the rest of the study because

the remaining questions depend on the stimuli embedded in the eye-tracking task. Thus, the terminated participants will be requested to return their submissions. In this case, their data will be removed. Given that participants will answer a few questions before they are directed to the webcam-based eye-tracking platform, partial payments will be made to those who encounter technical failures but not those who withdraw from the study.

7. Study Procedures

Given that this project consists of three parts: the screening survey, the main experiment, and the follow-up survey; below is a description of each part. No personally identifying information will be collected throughout the entire project. Only participants' Prolific IDs will be used to connect data across the three parts.

The screening survey: Potential participants from the Prolific will first be invited to participate in a short online screening survey. The screener will be built using the Qualtrics survey platform. We will prescreen the sample to some extent using the Prolific' existing prescreening options, including currently residing in the U.S., being at least 21 years old, drinking at least one unit of alcohol on average per week, and having webcam or built-in camera that they are willing to use as part of a study. The screening survey will include five questions related to their age, average weekly alcohol consumption, and technical support to complete eye tracking tasks. Participants must meet the following inclusion criterion to be invited to participate in the main experiment: 1) be at least 21 years old; (2) have consumed more than three alcoholic drinks per week over the past year; and (3) be willing to participate in remote eye tracking tasks and have necessary technical support and physical environment to complete remote eye tracking tasks. The entire duration of the screening survey is expected to be about 1 minute.

The main experiment: Eligible participants will be invited to participate in the main experiment through the Prolific site. Once they sign up for the main experiment, they will be redirected to the online experiment built in Qualtrics survey platform. Participants will be first asked to sign the consent form and provided details about the study purpose and procedure. They will be informed that they will need to turn on their cameras when completing the eye-tracking task. Although their faces and surroundings will be recorded during the remote eye-tracking task, the researchers will not have access to these recordings. Consented participants will first answer several questions designed to measure baseline tobacco and alcohol consumption, alcohol-related knowledge, and the device they are currently using to be directed to the corresponding mobile or desktop-based eye-tracking experiment. Next, participants will engage with a webcam-based eye-tracking task. They will first read instructions and tips related to completing the eye-tracking task. They will then go through a calibration procedure to ensure good tracking. Participants will then be randomly assigned to view an order-randomized stimulus set containing either three narrative PWLs or three non-narrative PWLs. Narrative PWLs will contain photos of cancer

patients, and non-narrative PWLs will include images of diseased organs. All PWLs will include a simple, clear warning statement (e.g., "WARNING: Drinking alcohol can cause oral cancer.") to describe the specific cancer risk associated with alcohol. Within each warning type, one will focus on oral cancer, one on esophageal cancer, and one on larynx cancer. All three cancers have higher relative risks for moderate and heavy drinkers compared to other types of cancer linked to alcohol. Participants will be instructed that the image will be displayed for 20 seconds and that they need to stay as still as possible while viewing. After viewing each PWL, they will proceed to answer questions designed to measure perceived attention, reactance, and narrative construction within the eye-tracking platform. After viewing all three PWLs, participants will answer additional questions about their and affective and cognitive responses toward the warnings, alcohol-related cancer risk perceptions and behavioral intentions, and policy support for the warnings. They will then answer a few questions designed to collect socio-demographic information at the end of the study. Upon completion of the study, participants will be debriefed. They will be reminded that they will be invited to participate in a follow-up survey in two weeks. The entire duration of the main experiment is expected to be about 15 minutes, with 5 minutes spent on completing the eye-tracking portion and 10 minutes on answering questions via the Qualtrics survey platform.

The follow-up survey: Participants who completed the main experiment will be invited to participate in the follow-up survey after two weeks. The follow-up survey will include questions about their behaviors related to drinking and the labels in the past two weeks. Risk perceptions, intentions, and policy support measured in the main experiment will be measured again to assess the long-term effect of narrative (vs. non-narrative) PWLs. The entire duration of the follow-up survey is expected to be about 5 minutes.

7.1. Data Collection/Instruments

The screening survey questionnaire, the main experiment questionnaire, the follow-up survey questionnaire, and the experimental stimuli (i.e., narrative and non-narrative PWLs) are included in the submission. Below, we briefly describe each questionnaire.

The screening survey: The screening survey will include five questions related to their age, average weekly alcohol consumption, and technical support to complete eye tracking tasks.

The main experiment: ***Pre-test measures*** will assess baseline tobacco and alcohol consumption and other alcohol-related background information. Baseline tobacco and alcohol consumption are included because the combination of tobacco and alcohol significantly increase the risk for developing cancers in mouth, esophagus, and larynx, the three cancer types shown in the experimental stimuli. Other *alcohol-related background information* will be included because they may influence how participants respond to the experimental stimuli. ***Post-test measures*** will assess visual attention measured via the eye-tracker and a self-report question, avoidance, narrative construction, and reactance in

response to each PWL, affective and cognitive responses after viewing all PWLs, risk perceptions, intentions to reduce and stop drinking, and policy support. The primary outcomes include attention, reactance, risk perceptions, and intentions, as stated in the hypotheses. The secondary outcomes include avoidance, narrative construction, affective and cognitive responses (i.e., processing fluency, affect, cognitive elaboration, and retrospective reflection), attitudes toward alcohol, intentions to forgo alcohol, intentions to avoid the warnings, and policy support for the warnings. The secondary outcomes are measured to explore the underlying psychological mechanisms of narrative (vs. non-narrative) PWLs. See the attached questionnaire for the self-report questions. Here, we describe how attention will be measured with the eye-tracker. Specifically, attention to each PWL will be measured with three eye tracking statistics: time until noticed, time viewed, and number of visits. Three areas of interest (AOI) will be defined a priori for each PWL, including (1) warning image, (2) warning text, and (3) entire warning label. All AOIs are consistent in size and location on each stimulus. Time until noticed measures the time between stimulus onset and the arrival of the participant's gaze into a specific AOI, which often reflects an AOI's ability to grab visual attention relative to other elements of a stimulus. Time viewed measures the average amount of time spent on an AOI, and it signals attention and cognitive processing. Number of visits measures the total number of unique times the AOI was viewed, which is an indicator of interest. Finally, socio-demographics will include questions related to their age, biological sex, gender identity, ethnicity, race, education, household income, political ideology, medical statistics literacy, and cancer history.

The follow-up survey: The follow-up survey will include questions related to their behaviors in the past two weeks, including drinking behavior change due to the labels, information seeking behaviors, and social interactions. Risk perceptions, attitudes, intentions, and policy support assessed in the main experiment will be measured again in the follow-up survey.

7.2. Locations/Facilities

This study will take place online, at a time and place that participants choose.

8. Risks/Benefits

8.1. Risks

Risk	Probability of Risk Occurring	Magnitude of Potential Harm	Duration of the Risk
A potential risk is discomfort and emotional distress when answering questions related to alcohol risks and/or viewing the experimental materials.	Occasional	Minimal	3-5 minutes when participants answer questions related to alcohol consumption and viewing the alcohol warning labels.

There is also a risk with regards to breach of confidentiality.	Rare	Minimal	Rare
There might be risks in protecting participants' privacy because their faces and surroundings will be recorded when engaging in the remote, webcam-based eye-tracking task.	Occasional	Minimal	2-3 minutes when participants engage in the webcam-based eye-tracking task.

8.2. Risk Mitigation

Risk	Strategies for Minimizing Risk
A potential risk is discomfort and emotional distress when answering questions related to alcohol risks and/or viewing the experimental materials.	This potential risk can be mitigated by (1) informing participants this potential risk in the consent form, (2) including a link to the CDC website on alcohol use at the end of the survey, and (3) informing participants that they have the right to withdraw at any time.
There might be risks in protecting participants' privacy because their faces and surroundings will be recorded when engaging in the remote, webcam-based eye-tracking task.	To mitigate this risk, participants will be ensured that their recordings will not be accessed by the researchers (Note: Tobii is responsible for any processing of personal data, and it will not transfer any personal data to the researchers.) They will also be instructed on where and how to sit in relation to the webcam's recording area. This is to ensure that the video capture is limited to those parts (e.g., face, head) of the participants that are necessary to complete the eye-tracking part. They will also be instructed to make sure that no other individuals are present for the duration of the study.

8.3. Data Safety Monitoring

The PI (Dr. Zexin Ma) and her collaborator (Dr. Joshua Haworth) will oversee the progress, safety, and data integrity of the trial on an ongoing basis. Adverse events are not anticipated, but any occurring will be documented and reported to the UConn and BRANY IRB within three business days. A cumulative summary of adverse events and study progress will be communicated to the BRANY IRB at continuing review.

8.4. Benefits

There may be no direct benefits to participants. Yet, the results of this study may benefit others in the future because they will contribute to the scientific understanding of the effectiveness of pictorial health warnings.

9. Data/Sample Management, Protection, and Record Keeping

To protect the confidentiality of the research data, no personal identifying information will be collected throughout the project. The screening data will be removed for participants who are not enrolled in the main research.

Because this is an NIIH-funded project, all the study materials and data will be made available to the research community in perpetuity free of charge through the Inter-University Consortium for Political and Social Research (ICPSR). We will use standard processing and documentation protocols adopted by the ICPSR for data formats, variable names, descriptions, and labels. Datasets will be findable and identifiable through a study digital object identifier (DOI) minted by ICPSR. Users of the public use data must register with ICPSR and agree to the Terms of Use, which are designed to protect study participants by limiting data use to scientific research and aggregate statistical reporting, prohibiting attempts to identify study participants, and requiring immediate reporting of any disclosure of study participant identity. Data users also agree not to share or redistribute any data downloads. Participants will authorize sharing of their de-identified data with other researchers through language on the consent form. All data will be de-identified.

Note that although the study will use webcam-based eye-tracking to measure participants' eye movements, the researchers will not have access to the recordings. The vendor, Sticky by Tobii, will be responsible for any processing of personal data, and it will not transfer any personal data to the researchers.

10. Dissemination

The PI will be responsible for handling ClinicalTrials.gov requirements for this project. I will register for the trial at ClinicalTrials.gov no later than 21 days after enrolling the first participant. Once a record is established, I will confirm the accuracy of record content, resolve problems, and maintain records including content update and modifications. I will also be responsible for submitting trial results no later than one year after the primary completion date. Informed Consent Documents for the clinical trial will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

This project is expected to produce multiple scientific manuscripts, which will be submitted to communication and public health conferences and peer-reviewed journals. Potential conference outlets include the annual conference of the International Communication Association, National Communication Association, and Society of Behavioral Medicine. Potential journal outlets include Human Communication Research, Communication Methods and Measures, Health Communication, Journal of Health Communication, Health Education & Behavior, American Journal of Public Health, and Social Science & Medicine.

11. Additional Considerations

11.1. Training and Supervision of Study Personnel

Besides the PI, there are two personnel on this project. Dr. Joshua Haworth is an expert on eye-tracking, and he will work closely with PI for the experiment design, data collection, data analysis, and manuscript write-up. Dr. Jun Hu serves as the statistical consultant for this project, and he will provide consultancy on the data analysis. Both Drs. Joshua Haworth and Jun Hu have the necessary expertise and skills to perform their work.

11.2. Protocol Deviations

A potential protocol deviation is related to the sample size. As mentioned, we plan to screen 1,200 participants and enroll 500 participants for the main study. If we do not have 500 eligible participants signed up for the main study after screening 1,200 participants, we will need to continue the screening study. Similarly, if we do not have 213 completed participants to achieve a statistical power of .80, we will also need to continue the screening study and enroll more participants in the main experiment. In addition, if participant demographic distribution does not approximate the demographics of the general population in the United States (e.g., not enough racial minority participants), we will recruit participants from the specific populations on Prolific for the screening survey and the main study until the sample approximates the U.S. demographics. We will report the protocol deviations to the BRANY IRB following their policies and procedures.

Another potential deviation is related to the experiment stimuli. The stylistic design of the PWLs may be changed, such as adding a boarder to each PWL or using a black background and white text (the current version uses a white background and black text). However, the content of the image and text will remain the same.

11.3. Unanticipated Problems

An unanticipated problem could be an actual breach of participants study information. When this unanticipated problem occurs, we will report it to the BRANY IRB following their policies and procedures.