STUDY PROTOCOL

Know Your Limits: How does alcohol labelling influence knowledge, attitudes and behaviour?

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Background

Alcohol use is a major public health issue. It is associated with over 200 health problems and accounts for almost 6% of all mortality and morbidity (World Health Organisation, 2009). A review of the alcohol trade press showed that the alcohol industry has used alcohol packaging as a promotional tool for decades, and is important in influencing drinking behaviour, brand awareness and even taste (Stead, Angus, Macdonald, & Bauld, 2014). To minimise alcohol’s harms, we can use the same features to reduce consumption instead.

Policy makers recognise the importance of alcohol labelling interventions, and in 2015 the European Parliament and the UK House of Lords European Union (EU) Committee called on the EU to “make it mandatory for labelling on alcoholic beverages to include information on the strength, the ingredients, nutrition, and the dangers of drinking during pregnancy” (European Parliament, 2015; European Union Committee, 2015). In 2011, the alcohol industry pledged to place clear labelling on at least 80% of products as part of the Responsibility Deal. However, a recent report has found that the industry has fallen short of this target both in terms of the extent and quality of this voluntary labelling (Institute of Alcohol Studies, 2015). Statutory regulation may be a feasible method of ensuring alcohol labelling is “clear, concise and effective” (Institute of Alcohol Studies, 2015). Our (currently unpublished) interviews with key stakeholders, including medical professionals and policymakers, indicate that effective statutory regulation would rely on consumer acceptance of labelling legislation.

Despite political support, there is a dearth of research on the effectiveness of alcohol labelling interventions (i.e., alcohol units and health warning information) for reducing alcohol consumption (Hollands et al., 2013). Australian research has shown that ‘standard drink’ labelling (similar to UK ‘unit’ labelling) is effective in educating drinkers about the alcoholic content of beverages (Osiowy, Stockwell, Zhao, Thompson, & Moore, 2015; Tim Stockwell, 1994; Tim Stockwell, Blaze-Temple, & Walker, 1991; Timothy Stockwell, Blaze-Temple, & Walker, 1991) However, focus groups have suggested that unit information may paradoxically facilitate choice of high alcohol content beverages, particularly among young male alcohol consumers (Jones & Gregory, 2009). Similarly, although there is some evidence that alcohol warning labels increase awareness of the risks of drinking (Thomas K Greenfield, Graves, & Kaskutas, 1993; Thomas K. Greenfield & Kaskutas, 1993; MacKinnon, Pentz, & Stacy, 1993), there is little research into what messages warning labels should present.
We will examine how alcohol labels, communicating alcohol unit content and alcohol related health warnings, influence attitudes and beliefs towards drinking, behavioural intentions and alcohol choice behaviours, and examine whether there are any unintended consequences of presenting this information.

**Study Objective and Hypotheses**

The primary research questions to be addressed are:

1. What is the best method of presenting unit information?

We will examine the impact of four unit presentation methods (see Table 2 for details) on five outcome measures: 1) the overall speed and accuracy of calculating the number of units in alcoholic beverages, 2) healthier (i.e., lower strength) drink choice, 3) self-efficacy to drink less, 4) response-efficacy (i.e., belief that reducing alcohol consumption would improve health), and 5) alcohol craving (see Table 1 for all outcome measures). The accuracy of alcohol unit calculations will be our primary outcome measure.

2. What is the best method of presenting health warning information?

We will examine the impact of three aspects of health warning design: 1) health message (i.e., cancer vs mental health), 2) framing (i.e., negative consequences of drinking vs positive benefits of cutting down), and 3) specificity (i.e., a general vs specific message) (see Table 3 for details). We will examine seven outcome measures: 1) reactance to warnings, 2) avoidance of warnings, 3) warning believability, 4) motivation to drink less, 5) self-efficacy, 6) response-efficacy, and 7) alcohol craving. Motivation to drink less will be our primary outcome measure.

Secondary research questions to be addressed are:

3. Are there differences in responses to unit information and health warning labelling according to gender, age and problematic alcohol use?

4. Does support for alcohol labelling influence responses to alcohol health warnings, and how does this support change after viewing labels?

**Study Design**

This will be an online between-subjects experiment with two tasks. Participants will be randomised to one of four unit conditions in the first task and one of eight health warning label conditions in the second task. Task order will not be randomised as this is not possible using the software. As shown in Table 3, the eight warnings are composed from the three factors (health message, framing, specificity) each with two levels.

**Study Site**

The study will be conducted online and will be designed and hosted on the Qualtrics online survey platform (http://www.qualtrics.com/).

**Participants and Recruitment**

Alcohol consumers (n = 1,900, 50% female and 50% male) will be primarily recruited from the current sample of participants on Prolific Academic (https://www.prolific.ac/). The study will also be advertised more widely via the TARG email mailing list, the TARG website and social media and interested individuals will be directed to the Prolific Academic site. Those who want to take part will read an information statement before giving their consent to participate. Equal numbers of males and
females will be recruited \((n = 950)\). This will be achieved by creating identical, but separate online experiments for male and female participants.

The experiment is expected to take approximately 10 minutes to complete and participants will be reimbursed £1 on completion. This is in line with recommended reimbursement amounts from Prolific Academic.

Participants who begin the experiment but do not complete it will not be reimbursed. In addition, those who report not drinking alcohol (which will be assessed immediately after consent is given) will not complete the experiment and will not be reimbursed. Participants will be informed of this in the information statement.

**Inclusion criteria**

- At least 18 years of age (assessed in pre-screening questions on Prolific Academic);
- Live in the UK (assessed in pre-screening questions on Prolific Academic);
- Report drinking alcohol (assessed in the first question in the experiment).

**Sample size determination**

The sample size for the study has been calculated based on the primary outcome measure for the health warning task (motivation to drink less), in order to detect a difference in the main effect of one of the factors in the health warning design (i.e., health warning framing) at 95% power and an alpha level of 1%. To detect a difference in motivation to drink less across participants in the two health warning conditions of 0.5 \((SD = 2\); based on a 1-5 scale), which is equivalent to an effect size of \(d = 0.25\), we will require a total of 1,786 participants. We will recruit 1,900 participants to account for exclusions based on participants failing attention checks (see below).

**Withdrawal of participants**

Participants will be informed that they are able to withdraw from the experiment at any time by leaving the experiment webpage. None of their data will be saved if they do this. However, participants who withdraw will not be reimbursed. Upon completion of the experiment, participants’ data will be anonymised with a unique numeric identifier and therefore participants will not be able to withdraw their data at a later point. Participants will be made aware of this in the information statement.

**Randomisation**

Qualtrics will be used to pseudo-randomise participants into the different experimental conditions (i.e., one of four unit information conditions and one of eight health warning conditions) such that an equal number of participants are in each condition. The presentation order of questions in the health warning task will be randomised by Qualtrics.

**Measures and Materials**

Questionnaires: demographics, drinking behaviour and support for alcohol labelling

Participants will first report whether they consume alcohol with the question ‘Do you drink alcohol?’, with the options ‘Yes’ and ‘No’. Those participants answering ‘No’ will be taken to the end of the experiment and will not be reimbursed.

We will use a pre-screening feature on Prolific Academic to ensure that those not reporting being 18 or over and not living in the UK are unable to complete the study. However, participants will also provide demographic information including age, gender, and where they currently live (with the
options of: ‘England’, ‘Wales’, ‘Scotland’, ‘Northern Ireland’, ‘Other (please specify)’ and ‘I do not live in the UK’). Participants who report that they are under 18, do not live in the UK or report being of a different gender to that specified in pre-screening will be taken to the end of the experiment and will not be reimbursed.

Support for alcohol labelling legislation will be assessed by asking participants to what extent they agree with the following statements: 1) ‘Alcoholic beverages should include more information about alcohol strength (i.e., unit information)’, 2) ‘Alcoholic beverages should have information about the health impact of drinking (i.e., health warning labels)’, and 3) ‘Alcoholic beverages should include more nutritional information (i.e. calorie information)’. These three questions will be answered using a 100-point visual analogue scale with the anchors ‘STRONGLY DISAGREE’ and ‘STRONGLY AGREE’.

Participants will report their highest qualification attained (with the options of ‘Higher Education or professional/vocational equivalents’, ‘A levels or vocational level 3 or equivalents’, GCSE/O Level grade A*-C or vocational level 2 or equivalents’, ‘Qualifications at level 1 and below’, ‘Other qualifications: level unknown’ and ‘No qualifications’) (ONS, 2015). Participants will also be asked whether they are currently a university student (with the options of ‘Yes’, ‘No’) and students will state what type of course they study (with the options of ‘Undergraduate’, ‘Postgraduate’).

Level of problematic alcohol use will be assessed using the Alcohol Use Disorders Identification Test (AUDIT) (Bohn, Babor, & Kranzler, 1995).

Unit information task and stimuli

Participants will be assigned to one of four unit label conditions (see Table 2 for images of these labels):

1. **ABV and volume** – Alcohol by volume (%) and bottle volume, which is the minimum legal requirement for alcohol labels (this information will also be included in the other conditions).
2. **Total units in bottle** – This is one of the key labelling elements agreed as part of the Responsibility Deal.
3. **Unit number per serving** – Similar to food labels, this will include the percentage of one’s guideline weekly number of units per serving.
4. **Pie chart of guideline weekly amount** – This is a novel unit labelling method, which displays the proportion of one’s weekly units that a single serving of an alcohol beverage is.

Participants will complete two tasks / questions in response to the label. A full list of outcome measures can be found in Table 1.

To examine if unit labelling can improve **conceptual understanding** of units and weekly drinking guidelines, participants will see an information screen before being shown four alcoholic beverages (see Table 2) alongside unit labelling information according to the beverage and their condition. The four beverages will reflect the most popular drink types and brands in the UK and the presentation order of the four beverages will be randomised. Participants will be asked: ‘How many [serving name (XX ml)] of this [wine / cider / vodka / beer] could you have in a week before reaching the recommended limit of 14 units per week?’ The accuracy of this estimate will be the primary outcome measure for the unit information task. We will also measure the time taken to make the response (participants will be asked to ‘answer as quickly and as accurately as you can’, and told that they must not use a calculator).
Figure 1: Example beer and labels for drink choice task

To examine the impact of unit labelling on drink choice, participants will be presented with three bottles of beer, of three non-UK (i.e., relatively unfamiliar) brands, simultaneously on screen, each with the unit label as per their randomly assigned condition (see Figure 1). The three beers will be of different alcohol strengths: 4%, 5% and 6%. Participants will be asked ‘Which beer would you choose to drink?’ Participants will be required to click on one of the beers. The strength information will be counterbalanced between each the three beer brands to control for any systematic brand preferences.

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Treatment of data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unit labelling</strong></td>
<td></td>
</tr>
<tr>
<td>1. Conceptual understanding of units and weekly drinking guidelines</td>
<td></td>
</tr>
<tr>
<td>a. Accuracy of weekly guidelines estimate*</td>
<td>Participant estimate minus actual value</td>
</tr>
<tr>
<td>b. Overall speed of estimates</td>
<td>Time taken to provide weekly guidelines estimates</td>
</tr>
<tr>
<td>2. Drink choice</td>
<td>Raw value (choice of the low, medium or high strength drink)</td>
</tr>
<tr>
<td>3. Self-efficacy regarding drinking less^</td>
<td>Raw value</td>
</tr>
<tr>
<td>4. Response-efficacy regarding drinking less^</td>
<td>Raw value</td>
</tr>
<tr>
<td>5. Alcohol craving (AUQ) ^</td>
<td>Total of all questions</td>
</tr>
<tr>
<td><strong>Health warning labelling</strong></td>
<td></td>
</tr>
<tr>
<td>1. Reactance to warning</td>
<td>Mean of three questions</td>
</tr>
<tr>
<td>2. Avoidance of warning</td>
<td>Mean of three questions</td>
</tr>
<tr>
<td>3. Believability of warning</td>
<td>Raw value</td>
</tr>
<tr>
<td>4. Motivation to drink less*</td>
<td>Raw value</td>
</tr>
<tr>
<td>5. Self-efficacy regarding drinking less^</td>
<td>Raw value</td>
</tr>
<tr>
<td>6. Response-efficacy regarding drinking less^</td>
<td>Raw value</td>
</tr>
<tr>
<td>7. Alcohol craving (AUQ)^</td>
<td>Total of all questions</td>
</tr>
</tbody>
</table>

* Indicates primary outcome measures ^ indicates question asked once at the end of the experiment
Table 2: Unit presentation conditions

<table>
<thead>
<tr>
<th>Alcohol bottle stimuli</th>
<th>Unit Condition 1</th>
<th>Unit Condition 2</th>
<th>Unit Condition 3</th>
<th>Unit Condition 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardy’s – white wine</td>
<td>ABV 11.5% 750ml</td>
<td>8.6 Units</td>
<td>Units 2.0</td>
<td>One medium glass (175 ml) contains:</td>
</tr>
<tr>
<td>750ml</td>
<td></td>
<td></td>
<td></td>
<td>A medium glass (175 ml) contains:</td>
</tr>
<tr>
<td>11.5% ABV</td>
<td></td>
<td></td>
<td></td>
<td>2.0 units</td>
</tr>
<tr>
<td>8.6 units per bottle</td>
<td></td>
<td></td>
<td></td>
<td>Of your guideline weekly amount</td>
</tr>
<tr>
<td>2.0 units per 175 serving</td>
<td></td>
<td></td>
<td></td>
<td>14%</td>
</tr>
<tr>
<td>Stella Artois – beer</td>
<td>ABV 4.8% 284ml</td>
<td>1.4 Units</td>
<td>Units 1.4</td>
<td>One bottle (284 ml) contains:</td>
</tr>
<tr>
<td>284ml</td>
<td></td>
<td></td>
<td></td>
<td>A bottle (284 ml) contains:</td>
</tr>
<tr>
<td>4.8% ABV</td>
<td></td>
<td></td>
<td></td>
<td>1.4 units</td>
</tr>
<tr>
<td>1.4 units per bottle</td>
<td></td>
<td></td>
<td></td>
<td>Of your guideline weekly amount</td>
</tr>
<tr>
<td>1.4 units per serving</td>
<td></td>
<td></td>
<td></td>
<td>10%</td>
</tr>
<tr>
<td>Strongbow – cider</td>
<td>ABV 5% 2L</td>
<td>10.0 Units</td>
<td>Units 2.8</td>
<td>One pint (568 ml) contains:</td>
</tr>
<tr>
<td>2000ml</td>
<td></td>
<td></td>
<td></td>
<td>A pint (568 ml) contains:</td>
</tr>
<tr>
<td>5% ABV</td>
<td></td>
<td></td>
<td></td>
<td>2.8 units</td>
</tr>
<tr>
<td>10 units per bottle</td>
<td></td>
<td></td>
<td></td>
<td>Of your guideline weekly amount</td>
</tr>
<tr>
<td>2.8 units per pint serving</td>
<td></td>
<td></td>
<td></td>
<td>20%</td>
</tr>
<tr>
<td>Smirnoff – vodka</td>
<td>ABV 40% 700ml</td>
<td>28.0 Units</td>
<td>Units 1.0</td>
<td>One single measure (25 ml) contains:</td>
</tr>
<tr>
<td>700ml</td>
<td></td>
<td></td>
<td></td>
<td>A single measure (25 ml) contains:</td>
</tr>
<tr>
<td>40% ABV</td>
<td></td>
<td></td>
<td></td>
<td>1.0 units</td>
</tr>
<tr>
<td>28 units per bottle</td>
<td></td>
<td></td>
<td></td>
<td>Of your guideline weekly amount</td>
</tr>
<tr>
<td>1.0 unit per serving</td>
<td></td>
<td></td>
<td></td>
<td>7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Of your guideline weekly amount</td>
</tr>
</tbody>
</table>
Health warning task and stimuli

Based on previous research (Pettigrew et al., 2014) and our interviews with medical professionals regarding health warning design, health warning messages will be developed using three factors: message specificity (general vs specific), message framing (positive vs negative) and message content (cancer vs mental health), creating a total of eight health warnings (see Table 3). After randomisation to one of the unit conditions (as described above), participants will then be randomised to view one of the eight health warnings presented on a non-UK branded bottle of beer (see Figure 2). They will then answer a series of questions, the order of which will be randomised between participants, to measure their reactance, avoidance and believability of the warning and their motivation to drink less (Noar et al., 2015).

Figure 2: Example health warning label

To measure reactance to the warning, the Brief Reactance to Health Warnings Scale (BRHWS) will be administered (Hall et al., 2017). Participants will rate the extent to which they agree that ‘This warning is trying to manipulate me’, ‘The health effect on this health warning is overblown’ and ‘This warning annoys me’. Agreement with reactance statements will be scored on a five-point scale from ‘STRONGLY DISAGREE’ (coded as 1) to ‘STRONGLY AGREE’ (coded as 5).

Avoidance of the warning will be measured with three items, preceded by the text ‘Imagine that all alcohol containers had this warning’ 1) ‘How likely is it that you would try to avoid thinking about the warning?’ 2) ‘How likely is it that you would try to avoid looking at the warning on your drink?’, and 3) ‘How likely is it that you would keep the drink out of sight to avoid looking at the warning?’ Questions will be answered on a five-point scale from ‘NOT AT ALL LIKELY’ (coded as 1) to ‘EXTREMELY LIKELY’ (coded as 5).

To assess the believability of the warning, participants will be asked ‘How believable is this health warning?’ This question will be answered on a five-point scale from ‘NOT AT ALL BELIEVABLE’ (coded as 1) to ‘EXTREMELY BELIEVABLE’ (coded as 5).

To measure motivation to drink less, participants will be asked ‘Does this health warning make you feel motivated to drink less?’ This question will be answered on a five-point-scale from ‘STRONGLY DISAGREE’ (coded as 1) to ‘STRONGLY AGREE’ (coded as 5) (adapted from (Wakefield et al., 2017)). This will be our primary outcome measure as recent research has used this measure to assess responses to anti-alcohol advertisements (Wakefield et al., 2017).
Table 3: Health warning messages

<table>
<thead>
<tr>
<th>General</th>
<th>Specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negatively framed</td>
<td>Positively framed</td>
</tr>
<tr>
<td>Cancer</td>
<td>Alcohol increases your risk of cancer</td>
</tr>
<tr>
<td>Mental health</td>
<td>Alcohol increases your risk of mental illness</td>
</tr>
</tbody>
</table>

Self-efficacy, response efficacy and alcohol craving

To assess self-efficacy, participants will be asked ‘For me cutting down on the number of alcohol units that I drink in the next week would be…‘VERY DIFFICULT’ (coded as 1) to ‘VERY EASY’ (coded as 5).

To assess response-efficacy, participants will be asked, ‘To what extent do you think that cutting down on your drinking would reduce your risk of alcohol-related disease?’ Questions will be answered on a five-point scale from ‘NOT AT ALL LIKELY’ (coded as 1) to ‘EXTREMELY LIKELY’ (coded as 5).

To assess alcohol craving, participants will compete the Alcohol Urges Questionnaire (AUQ). The AUQ is an 8-item measure of drinking urges, answered on a 7-point Likert-type scale (Bohn, Krahn, & Staehler, 1995).

Procedures

Participants will be recruited using Prolific Academic, which provides participants with a link to the study on the Qualtrics platform. The experiment will only be compatible with desktop and laptop devices to ensure the stimuli are readable. Participants will first be shown an information statement explaining the experiment and what they will be required to do. Participants will be informed that they are able to withdraw from the experiment at any time by closing their browser. Before commencing the experiment, participants will complete a tick-box consent page.

Participants will then complete the screening demographic questions and report their support for alcohol labelling policies. They will then complete the unit information and health warning tasks, in that order. Participants will then complete the questions regarding self-efficacy, response efficacy and alcohol craving. This section will include one attention check question, which will ask participants to select a particular option (‘This is an attention check question, please select the ‘extremely likely’ option’). Finally, participants will again report their support for alcohol labelling policies, complete the AUDIT and educational attainment and student status will be assessed.

Participants will then be presented with a debriefing screen including information about how they can find more information if they wish to. They will also be given the Principal Investigator’s details again if they wish to contact them. The debriefing screen will also be shown to participants who start the experiment but are then ineligible to complete it based on whether they consume alcohol and their reported gender, age and area of residence.
Statistical Plan

Data screening

Data will be collected on Qualtrics and extracted for analysis using SPSS. Participant data will be examined prior to analysis to ensure that participants who fail either of the attention check question (described in ‘Procedures’) are removed from further analyses.

Analysis

Research question 1: What is the best method of presenting unit information?

We will conduct a between subjects one way ANOVA with four levels on all outcomes shown in Table 1 under ‘Unit labelling’ other than ‘drink choice’. Our primary outcome measure will be accuracy of weekly guidelines estimates. To examine the impact of the four unit label conditions on drink choice, we will report the proportions of each group choosing the three different drinks. We will use logistic regression to examine the impact of unit label condition on the odds of choosing the lower unit drink.

Research question 2: What is the best method of presenting health warning information?

We will conduct a 2 (message specificity) × 2 (message content) × 2 (message framing) between subjects ANOVA on each of the outcome measures described in Table 1 under ‘Health warning labelling’. Our analyses are powered to detect only main effects rather than interactions. Our primary outcome measure is motivation to drink less.

Research question 3: Are there differences in responses to unit information and health warning labelling according to gender, age and problematic alcohol use?

In exploratory analyses, we will include age, gender and problematic alcohol use (AUDIT score) separately into the ANOVAs described above.

Research question 4: Does support for alcohol labelling influence responses to alcohol health warnings and how does this support change after viewing labels?

Exploratory analyses will examine whether support for alcohol labelling policies (as measured at the beginning of the study) is related to responses to the health warnings including: 1) reactance, 2) avoidance, 3) believability of the warning, and 4) motivation to drink less as a result of the warning, using a series of linear regressions. We will also examine whether support for alcohol labelling changes before and after the study and whether there are differences by unit and health warning condition using ANOVA.

Ethical Considerations and Informed Consent

Ethics approval has been obtained from the Faculty of Science Research Ethics Committee at the University of Bristol (ethics approval code: 23051753685). The study will be conducted according to the revised Declaration of Helsinki (2013) and the 1996 ICH Guidelines for Good Clinical Practice E6(R1). The participant will receive information at the start of the survey. The study will be closed online once the required number of participants have been recruited. Therefore, participants will be given sufficient time to read the information, consider any implications, and raise any questions with the investigators prior to deciding to participate. Consent will then be obtained. Participants will be informed that they are free to withdraw at any time.


**Safety**

As this is an online experiment we do not foresee any risks to participants.

**Data Management**

Data will be collected and processed in accordance with the principles of the Data Protection Act 1988.

**Anonymised study data**

All study data will be anonymised using a unique numeric identifier. Study data will be stored on an encrypted cloud server after completion. The data may only be accessed via a secure website which requires log-in credentials. Only study personnel will have access to these data. At the end of the study, electronic study data (including finalised data sheet) will be transferred to a designated University of Bristol Research Data Storage Facility for long-term archiving. Study data will be kept for a minimum of 15 years. At the appropriate time the data sheet will be locked and made open using the University of Bristol Research Data Repository.

**Screening documents and participant contact details**

No identifiable information will be collected from participants.

**Revoked data**

Participants will not provide their name and as participants are not aware of their unique ID number researchers will have no way to connect them with their data to revoke it. Participants will be informed of this before taking part in the study.

**Quality Control and Quality Assurance**

The investigators will be responsible for data quality. After collecting approximately 5% of the data, data collection will be paused to ensure information is being collected as expected. Data will be examined prior to analysis to check that participants are answering correctly, e.g. by not giving the same answer repeatedly.

**Insurance**

This study will be sponsored by the University of Bristol. The University of Bristol has Clinical Research Insurance to cover the liability of the University to research participants.

**Publication Policy**

The findings from this research study may be published in an appropriate scientific journal (and made available open access), and/or presented at an appropriate meeting. Study data will be collected and held by the study investigators. The data will be made available for sharing via a University of Bristol online data repository.

**Study Personnel**

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Conflicts of Interest

There are no conflicts of interest.

References


