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STUDY PROTOCOL

Effects of health warning glassware on alcohol consumption, alcohol urges and alcohol-related attitudes

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Background

It is estimated that around 10 million people in England regularly drink more than the recommended weekly low risk guidelines (Health and Social Care Information Centre, 2015). This is a growing public health concern, given that alcohol consumption is associated with over 200 health conditions (World Health Organisation, 2014). A survey from our own laboratory found that fewer than one in seven people were aware of the low risk guidelines, which limits drinkers' ability to follow them. The UK House of Lords EU Committee has identified that alcohol product labels may be an untapped communication channel for health information. However, legislation requiring alcohol labels to carry health warnings would be slow to implement. Furthermore, consumers may not attend to labels on bottles or may not come into contact with them on many drinking occasions (e.g., when buying glasses of wine or beer from bars). As part of an MRC-funded project, we have developed glasses that carry health warning labels, which circumvent these issues. This study will investigate whether drinking from glasses displaying health warnings affects drink behaviour and other alcohol-related outcomes.

Study Objective and Hypotheses

To test the effect of health warning glassware on alcohol consumption, alcohol urges and alcohol-related attitudes.

H1: Participants exposed to health warning glassware will drink less alcohol compared to participants exposed to control glassware.

H2: Participants exposed to health warning glassware will report lower alcohol urges compared to participants exposed to control glassware.

H3: Participants exposed to health warning glassware will report differences in alcohol-related attitudes (i.e., lower social acceptance, increased awareness of health consequences, and more motivation to control own drinking) compared to participants exposed to control glassware.

Study Design

This study will use a between-subjects design in which participants will be randomised to drink from a glass showing a health warning label or a control glass (no image). Group allocation will be randomised, but groups will contain equal numbers of participants.

Study Site

School of Experimental Psychology at the University of Bristol.

Participants and Recruitment

We will recruit 84 male and female alcohol consumers (defined as drinking alcohol at least once per week and include beer as a drink of choice). Participants will be aged between 18 and 40 years and attend one session of approximately 40 minutes. They will be recruited from the staff and students at the University of Bristol, and the general population via existing email lists, group websites, poster and flyer advertisements, and by word of mouth. Individuals who report interest in the study will be asked some eligibility questions. Those who meet the study inclusion criteria will be sent the information sheet and invited to a study session.

Participants will be required to not drink alcohol 24 hours prior to the study session. On completion of the study, participants will be reimbursed £7. Participants who are undergraduate students within the School of Experimental Psychology at the University of Bristol can opt for course credits instead of monetary reimbursement.

Inclusion criteria

- Regular alcohol consumers (defined as at least one alcoholic drink per week).
- Drinks beer as a drink of choice.
- English as first language or equivalent level of fluency.
- Aged between 18 – 40 years inclusive.

Exclusion criteria

- Current or past alcohol use disorder or alcoholism.
- Pregnancy or breastfeeding (self-report, but all female participants will be offered urine-based pregnancy test if there is any doubt)
- Uncorrected visual or auditory impairment.

- Alcohol consumption within 24 hours of study session

Sample size calculation

In a previous study that compared drinking rate from either curved or straight glasses, there were longer drinking times from straight glasses (mean (*M*) = 11.5, standard deviation (*SD*) = 5.6) compared to curved glasses (*M* = 7.2, *SD* = 3.3). This indicated an effect size of *d* = 0.9 (Attwood et al., 2012). We require a total sample of 84 participants (42 per group) to observe a more conservative effect *d* = 0.8 on total consumption with 95% power at an alpha level of 5%. This would be equivalent to a difference in total amount consumed of around 30 ml (*SD* = 40).

Withdrawal of participants

Participants will be informed that they are able to withdraw from the study at any time. Full reimbursement will be given if a participant experiences an adverse event or adverse reaction. For all other withdrawals (i.e., that are not due to an adverse event) we will reimburse an amount commensurate with the amount of time they have spent in the study.

Randomisation

We will use a randomly generated list to assign participants to the health warning glassware condition or control group. We researcher will create a randomisation list for 84 participants using random number generator software (www.randomizer.org) where each participant will be randomly assigned either the number '1' or '2' to indicate either the health warning glassware condition or control group. Finally, questions will be shown randomly for each questionnaire.

Measures and Materials

Glasses

Glasses will be pint glasses labelled with either a health warning (Figure 1) or no image (i.e., blank glass). The health warning will be a cancer warning that has been adapted from Eurocare's (2012) library of health warnings labels with their permission.

Figure 1. Health warning labelled glassware

Alcohol use and urges

The Alcohol Use Disorder Identification Test (AUDIT) (Saunders et al. 1993) will be administered to measure levels of alcohol misuse and record how much alcohol participants consume on an average week. Alcohol craving will be measured (at beginning and end of session) using the Alcohol Urges Questionnaire (Bohn et al. 1993). To measure actual consumption, participants will be given ten minutes to consume as much of the drink as they wish (while completing a filler task). We will measure the amount consumed (ml).

Alcohol-related attitudes

Participants will answer questions on alcohol-related attitudes within three domains: social norms, health and personal drinking (see below). These questions have been adapted from national surveys (Craig & Shelton 2007, Cotter et al., 2013) and validated questionnaires on motivation to change drinking behaviour (Boendermaker et al., 2016, Rollnick et al., 1992). All of these items will be rated on 100 mm visual analogue scales (VASs) ranging from strongly disagree (0) to strongly agree (100). A mean score will be calculated for each domain (reverse scoring as appropriate) and used in the analyses.

Social norms:

- Drinking is an important part of the British way of life
- People in some other parts of Europe tend to drink alcohol more sensibly than people in Britain
- There is nothing wrong with people getting drunk regularly
- The government should tax alcohol heavily to encourage people to drink less

Health:

- Regular moderate alcohol consumption can have serious health consequences in the long term
- Limiting alcohol intake helps prevent cancer
- Regularly drinking just above the recommended low risk guidelines (of 14 units/per week) won't significantly affect health
- Alcohol is only likely to affect the health of very heavy consumers

Personal drinking:

- The amount I drink at the moment is unlikely to have negative effects on my health
- I should be drinking less alcohol than I currently drink
- I would like to reduce the amount that I drink
- I would find it easy to reduce the amount that I drink (self-efficacy check)
- I plan to reduce the amount that I drink

Drink ratings (filler task)

Participants will answer eight questions rating liking, flavour intensity and choice, using 100 mm VASs ranging from not at all to extremely. The items will include:

- How tasty is this drink? (LIKING)
- How enjoyable is this drink? (LIKING)
- How pleasant is this drink? (LIKING)
- How refreshing is this drink? (LIKING)
- How intense is the flavour of drink? (INTENSITY)
- How much would you like to consume a full glass of this drink? (CHOICE)
- How likely would you be to buy this drink? (CHOICE)
- How likely would you be to choose this drink over other beers/wines?" (CHOICE)

Glassware rating: At the end of the session, all participants would be asked to rate the health warning glassware using the following items (100 mm VASs ranging from not at all to extremely):

- Adding alcohol-related health warnings to glasses is a good idea.
- These glasses would make me think more about the health effects of alcohol.
- These glasses would make me reduce the amount that I drink.
- Health warning glasses would be an effective health intervention.
- I would avoid looking at a health warning placed on a glass.

Procedures

Participants will be sent an information sheet prior to the study and invited to contact the researcher if they are interested in taking part. Basic eligibility will be assessed via email, and eligible participants will be invited to a test session. At the start of the session, each participant will be given the opportunity to read the information sheet again and ask questions, before giving informed consent. Participants will be asked to

sign two identical versions of the consent form: one they will take away and the other will be stored in the study folder. A short screening procedure will confirm eligibility. All female participants will be given the opportunity to take a pregnancy test (urine screen) at this point if there is any chance of pregnancy. Information collected from people who are ineligible will be destroyed in the University of Bristol's confidential waste facility.

Eligible participants will then complete baseline measures of craving (AUQ) and basic demographics (including AUDIT and alcohol consumption questions). Then participants will be served beer either in a glass printed with a health warning or a control glass (per the randomisation). Participants will be given 10 minutes to consume as much of the drink while completing a drink rating questionnaire. After 10 minutes, the researcher will return and remove the drink (the amount of liquid remaining will be measured). The craving measure (AUQ) will be completed again and participants will complete the alcohol-attitudes questionnaire. Participants will also be asked what they think the purpose of the study was, before being asked to complete the questions about the health warning glassware (the control group will be given a health warning glass at this point). Participants will then be debriefed and reimbursed for their time.

Drug Administration

All participants will be served 500 ml of beer (Becks 4.8% alcohol by volume; ABV) in pint (568 ml) glasses.

Statistical Plan

Data will be assessed for normality using skewness and kurtosis statistics. Where Mauchly's Test of Sphericity is violated (defined as $p < 0.05$), Greenhouse-Geisser corrected statistics will be reported.

The main statistical test that will be used on all primary outcome data (i.e., alcohol consumption, alcohol urges, alcohol attitudes – three domains) will be independent t-tests comparing outcomes in the health warning glass and control glass groups. Secondary analyses will explore whether responses to glassware differ between individuals drink above or below their recommended weekly guidelines (of 14 units), based on self-reported consumption, and among people who have high or low self-efficacy (item in personal drinking domain of attitudes questionnaire).

Ethical Considerations and Informed Consent

Ethics approval has been obtained from the Faculty of Science Research Ethics Committee at the University of Bristol (Approval Code: 64504). 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 investigator will explain the nature, purpose and risks of the study to the participant. The participant will receive the information sheet in advance of the study session. There will be no time restriction on how long participants take to respond, with the exception that participants who respond after all study places have been filled will not be offered a place on the study. Therefore, participants will be given sufficient time to read the

information, consider any implications, and raise any questions with the investigators prior to deciding whether to participate. On arrival at the study session participants will be given the opportunity to read the information sheet again and ask the investigator questions. Written consent will then be obtained. Participants will be informed that they are free to withdraw at any time.

Safety

Participants will be administered alcohol during the sessions (up to 500 ml of 4.8% alcohol by volume beer). As participants will all be regular alcohol consumers who drink beer as a drink of choice, we do not expect any adverse reactions. Participants will not need to drink all of the drink; they will be told they can drink as much or as little as they wish. Participants may experience some mild intoxication, however as this is one standard serving of beer we do not expect this to be excessive. To ensure the safety of our participants, they will know in advance of the study that they will be served this dose of alcohol, and therefore will be able to make any necessary arrangements. They will be advised that should stay behind until they feel the effects of alcohol have worn off and they shouldn't drive, operate heavy machinery or do anything that would be considered unsafe after drinking alcohol for the rest of the day. Participants will be asked to read and sign a post-study safety form to confirm that they understand these risks. We have standard operating procedures in place for adverse effects of alcohol (i.e., nausea, intoxication) and have facilities for people to stay behind until they feel ready to leave.

Adverse Event Reporting

Adverse events or adverse reactions will be documented at the end of the relevant session using an adverse event report, and will be recorded in the CRFs. The adverse event reports will be anonymised by unique study identifier and stored in the master file. Adverse events or adverse reactions will be followed up until resolved if possible. At the end of the study a safety report will be complied and sent to the Principal Investigator (PI) listing all adverse events and adverse reactions. All procedures related to adverse events will follow the University of Bristol adverse events policies and procedures.

Data Management

All aspects of the Data Protection Act will be adhered to. Consent forms will be retained by the School of Experimental Psychology for a period of 10 years after study completion. In the event that a participant revokes authorisation to collect or use personal health information, the investigator retains the ability to use all information collected prior to the revocation of participant authorisation.

Anonymised study data

Case report forms (CRFs) including participant questionnaires will be anonymised by a unique numeric identifier. CRFs will be stored in a locked office. All data requested on the CRF will be recorded. All missing data will be explained. If any entry errors are made, a single straight line will be drawn through the incorrect entry and the correct data entered above it; to correct such an error. All such changes will be initialled and dated. Relevant data will be transferred to an electronic data sheet and

the CRFs will be archived in the School of Experimental Psychology at the University of Bristol for 5 years.

At the end of the study, the 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

Screening documents, participant contact details and participant identifier logs will be stored separately in a study master folder and kept confidential. These will be kept in the study master folder for one year after study completion or until data are made open (whichever comes first), after which these documents will be destroyed. Failed screening documents will be shredded immediately using School's confidential waste facility.

Revoked data

If a participant decides that they do not want their data used after their participation they have the right to request that the data are withdrawn. They can request this up to one year after study completion or until the data are made open (whichever comes first).

Quality Control and Quality Assurance

The investigators will be responsible for data quality. After approximately 10% of data collection has been completed, the study will undergo an in-house quality assessment. During this monitoring process all CRFs and study documents will be assessed as well as the investigators laboratory management and participant engagement and corrected where necessary. Post-study checks will be conducted on data entry by an independent researcher. This researcher will re-enter 20% of hardcopy participant data. A threshold of 1% will be used, whereby error rates greater than 1% will require the data to be re-entered. A 100% check will be made on allocation to test condition.

Insurance

This study will be sponsored by the University of Bristol. The University has Clinical Research Insurance to cover the liability of the University to research participants. In the event that something goes wrong and a participant is harmed during the research study there are no special compensation arrangements. If a participant is harmed and this is due to someone's negligence then they may have grounds for a legal action for compensation against Bristol University or one of the other parties to the research, but they may have to pay their own legal costs.

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.

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Conflicts of Interest

The group have no relevant conflicts of interest.

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