behaviour change by design

Generating and Implementing Evidence to Improve Health for All

STUDY PROTOCOL

Straight-sided glasses for alcohol reduction: A randomised crossover trial in public houses and bars

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Abstract

Background

The aim of this study is to estimate the impact of serving lager, ale and cider in straight-sided glasses on alcohol consumption in public houses and bars.

Methods

Twenty-four public houses and bars in the UK will be recruited to take part in this cluster randomised multi-period crossover trial. All participating venues will perform two intervention periods (A) and two control periods (B) in a random order. Six venues will be randomised to each of the four possible orders: 1) BABA; 2) BAAB; 3) ABBA; or 4) ABAB. Each period will last two weeks and will involve serving lager, ale and cider in either straight-sided glasses (intervention condition) or the venue's usual glasses (control condition). Data on the volume (in ml) of lager, ale and cider sold will be collected and compared between intervention and control periods.

Discussion

The results of this study will provide evidence for the extent to which serving lager, ale and cider in straight-sided glasses can reduce the consumption of these alcoholic drinks in a naturalistic setting. This will have implications for local licensing policies which include strategies to reduce alcohol-related harm.

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Background

Excessive alcohol consumption is associated with increased morbidity and mortality, accounting for ~5.1% of the global burden of disease and injury (World Health Organisation, 2015). It is estimated to cost the National Health Service (NHS) ~£3.5 billion per year and society ~£21 billion per year (Health and Social Care Information Centre, 2015). Given the personal, societal and economic burden of excessive alcohol consumption it is unsurprising that alcohol control is high on the political agenda in many countries, including the UK. However, reducing population levels of alcohol consumption is notoriously difficult. Policies that reduce the affordability of alcohol have recently been found to be the most effective (Public Health England, 2016). However, these face strong opposition by both the UK government and the alcohol industry. Therefore, additional strategies are required.

Glass shape has been shown to influence the rate of alcohol consumption under controlled laboratory conditions. For example, social alcohol drinkers consumed lager more quickly from a curved glass than from a straight-sided glass (Attwood, Scott-Samuel, Stothart, & Munafò, 2012). This may be due to errors in perceptual judgement of the midpoint of the curved glass, resulting in drinkers perceiving themselves as drinking more slowly than they actually are and increasing their drinking rate accordingly. Increased drinking rate is likely to lead to higher overall alcohol consumption and therefore regulation of glass shape may be a modifiable target for intervention.

Study objective and hypothesis

The aim of this study is to estimate the impact of serving lager, ale and cider in straight-sided glasses on alcohol consumption in public houses and bars.

Hypothesis: A lower volume of lager, ale and cider will be sold when public houses and bars serve these alcoholic drinks in straight-sided glasses compared to their usual glasses.

Methods

Study design

Twenty-four public houses and bars in the UK will be recruited to take part in this cluster randomised multi-period crossover trial. All participating venues will perform two intervention periods (A) and two control periods (B) in a random order. Six venues will be randomised to each of the four possible orders: 1) BABA; 2) BAAB; 3) ABBA; or 4) ABAB. Each period will last two weeks and therefore the study will last eight weeks in total.

During the intervention condition, lager, ale and cider will be served in straight-sided pint and half pint glasses for two weeks. These glasses will be provided by the research team who will facilitate the exchange between usual and intervention glassware if required. The usual bar staff will be instructed on how to explain the change of glassware to customers if asked, without revealing the study aim or hypothesis.

During the control condition, lager, ale and cider will be served in the venue's usual pint and half pint glasses for two weeks (i.e., usual practice).

Study site

The study will be conducted in 24 public houses and bars in the UK.

Recruitment

Public houses and bars will be recruited by directly contacting publicans, as well as other key stakeholders from the alcohol industry (e.g., brewery companies and the National Union of

Students [NUS]). We will also attend monthly Pubwatch meetings across the UK and utilise personal contacts and snowballing.

Based on preliminary conversations with publicans, the following incentives will be offered to take part in the study: 1) get to keep the straight-sided intervention glasses for use after the study; and 2) publicity after study completion.

Inclusion criteria

- Sell more than 160 pints (i.e., 90 litres) of lager, ale and cider per week.
- Approximately 75% or more of their usual glasses for lager, ale and cider are curved (i.e., the width of the glass is not consistent all the way up).
- Their licensing conditions will allow them to serve lager, ale and cider in straight-sided pint and half pint glasses during the intervention condition.
- Have an electronic point of sale (EPOS) till system (or an equivalent) to record itemised sales for all drinks, including lager, ale and cider.

Sample size determination

This sample size calculation is based on our feasibility study (Troy, Maynard, Hickman, Attwood, & Munafò, 2015). If the study had consisted of a conventional two-period crossover design, a total of 24 public houses and bars would be required to allow a true mean difference in monetary takings of at least 0.6 standard deviations (SDs) to be detected between the intervention and the control condition, with 90% power and an alpha level of 5%. This calculation assumes a within-venue correlation coefficient of r = 0.65 across the two conditions. In our feasibility study, one SD equated to 27% of monetary takings across the three participating public houses. On this basis, we should be able to detect a mean difference in monetary takings of at least 16% between the two conditions.

Withdrawal of participants

Publicans will be informed that they are able to withdraw from the study at any time. See page 10 ('Revoked data') for details of handling withdrawn data.

Randomisation

The random order for the four periods (two intervention and two control periods) will be generated at the start of the study using a computer-generated list of random numbers. This list will be produced using STATA by an independent statistician who will email a member of the research team the order allocations in separate files (one for each of the 24 participating venues). After a venue has been recruited, the password-protected file relating to that recruitment number will be opened by a member of the research team and the venue will be allocated to one of four possible orders: 1) BABA; 2) BAAB: 3) ABBA; or 4) ABAB. Blocked randomisation will be used to ensure that an equal number of venues are assigned to each order (Figure 1).

It is not possible to blind the research team or the participating venues to order allocation, but the statistician conducting the analysis will be blinded. Bar staff and drinkers will also be blinded to the study hypothesis.

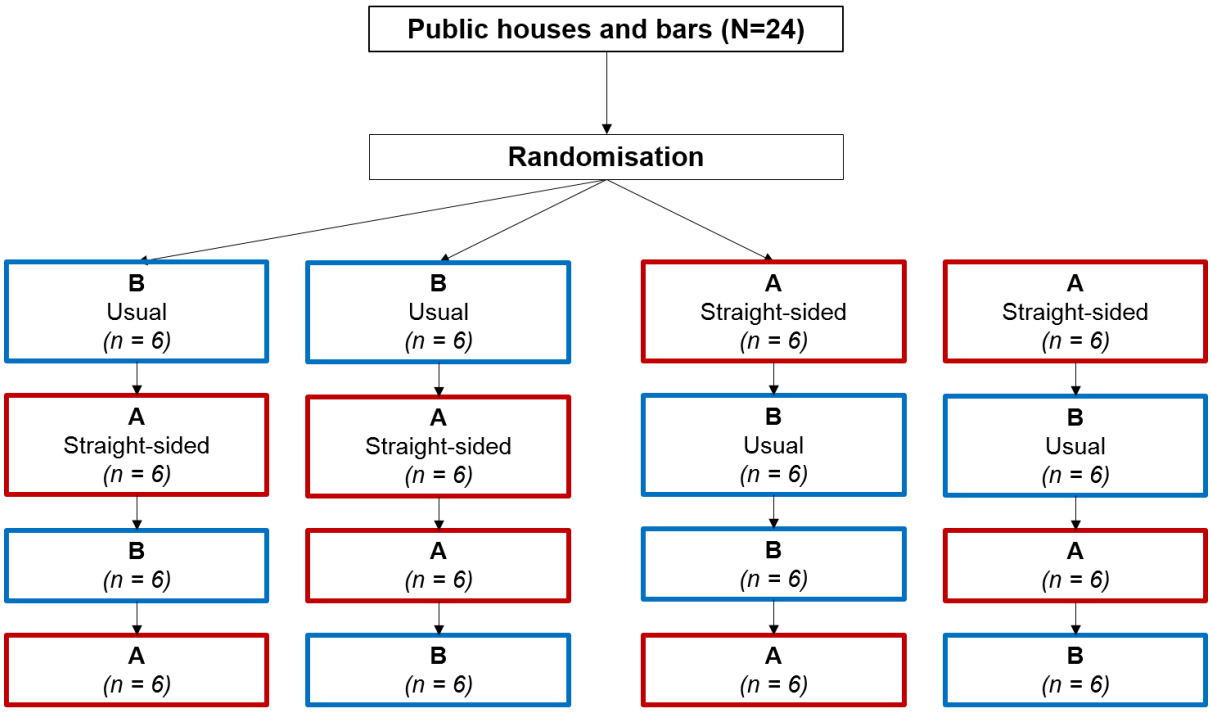

Figure 1. Random allocation.

All participating venues will perform two intervention periods (A) and two control periods (B) in a random order.

Materials and measures

Glasses

Public houses and bars will serve lager, ale and cider in either their usual pint and half pint glasses or straight-sided glasses provided by the research team. The key difference between the two glass shapes is that the width of the straight-sided glass is consistent all the way up (Figure 2).

A **B**

Figure 2. Straight-sided pint glass that will be provided by the research team (A) and examples of curved pint glasses (B).

Measures

Primary outcome

The primary outcome for this study will be the average volume (in ml) of lager, ale and cider sold, both daily and weekly, over each two-week period.

Secondary outcome

We will also examine the effects of the intervention on the consumption of wine, spirits and non-alcoholic drinks to explore whether customers choose a different drink as a result of not wishing to use the straight-sided glasses for lager, ale and cider.

Potential confounders

If drinkers leave the participating public houses and bars early to go for another drink elsewhere (e.g., due to not wishing to use the straight-sided glasses) we may erroneously interpret a reduction in volume sales as a reduction in overall alcohol consumption. Therefore, the total number of daily and weekly transactions during each period will be recorded by the publican and sent to the research team along with a record of their volume sales. Furthermore, once a week during each period a member of the research team will do a head count of customers. The day of the week and the time of day will be consistent across all four periods for each venue.

We will ask the publicans about special promotions and events both before and after each period. If these are consistent across all four periods, we will not discard any data. If these are present in one period but not the others, we will discard the affected day(s) for that period.

To account for between-venue variation in usual glassware (e.g., branding and curvature), we will take a picture of each participating venue's usual pint glasses for lager, ale and cider. We will also measure the difference (in mm) between the halfway point for each glass in terms of

height and the halfway point in terms of volume (this difference is 0 mm for a straight-sided glass).

Fidelity assessment

A member of the research team will conduct one fidelity check during each period (one every two weeks) to observe whether the intended glasses are being used (i.e., straight-sided glasses for the intervention condition and the venue's usual glasses for the control condition). The first fidelity check will take place within the first two days of each period to catch any problems early. All protocol breaches will be recorded and monitored. We will talk to the publicans of the public houses and bars with low fidelity to discuss ways of increasing protocol adherence. The fidelity checks will take place on days of the week that are usually busy (Friday or Saturday between 7pm and 10 pm) and will be conducted in conjunction with the head counts.

Follow-up

We may also conduct follow-up semi-structured questionnaires and / or interviews with publicans.

Procedures

The research team will directly contact publicans about the study and those who express an interest in taking part will be sent an information sheet. Publicans who wish to take part in the study will be contacted by the research team to arrange a date and time for visit one.

At visit one, a member of the research team will make sure the public house or bar meets the eligibility criteria. The researcher will show the publican the intervention glassware to make sure it is both practical (e.g., will fit in the dishwasher) and acceptable. The researcher will answer any remaining questions the publican may have and then written informed consent will be obtained from the publican. The researcher and the publican will arrange a date to start the study and the researcher will reveal the order of the four periods (two intervention and two control periods). The researcher will also record details of any special promotions and events that are due to take place during each two-week period.

During the intervention condition, the usual bar staff will serve lager, ale and cider in straight-sided pint and half pint glasses for two weeks. Bar staff will be instructed on how to explain the change of glassware to customers if asked. They will be instructed to say that the pub or bar is taking part in a research study for eight weeks which is being conducted by the University of Bristol and the University of Cambridge, the details of which will be revealed after study completion so as not to affect the results. The straight-sided glasses will be provided by the research team and the publican will be allowed to keep them for use after the study if they would like.

During the control condition, the usual bar staff will serve lager, ale and cider in the venue's usual pint and half pint glasses for two weeks.

Publicans will receive a telephone reminder on the day before each new period and the research team will facilitate the exchange between usual and intervention glassware if required. If necessary, they will also arrange external storage for the glasses that are not in use. If not-in-use glasses are being stored by the venue, during the fortnightly fidelity checks, a member of the research team will make sure they are being stored separately to the intended glasses (i.e., not on the shelves) to avoid confusion.

The publican will email the research team a record of both their daily and weekly takings at the end of each week, as well as the total number of daily and weekly transactions.

At the end of each period, a member of the research team will ask the publican about any special promotions and events that took place that were not recorded earlier.

Data collection will take place during any months of the year, unless a venue anticipates particularly high alcohol consumption during December or particularly low consumption during January.

Statistical plan

All participating venues will be required to complete at least two intervention periods and two control periods, resulting in 96 (24 x 4) observations of volume sales. We propose to use either the sales values or their log-transformed values to fit a general linear model, in which we will allow for the possible effects of the venue, the month, the period within the month, and crucially the shape of glass used. We will investigate potential carryover effects by fitting a treatment x period interaction, as well as other possible interactions between period, month and treatment. By having eight weeks of data on volume sales, we will be able to allow for carryover effects if they exist. *P*-values will be reported alongside 95% confidence intervals (CI).

We will also report the percentage difference in volume sales between the two intervention periods and the two control periods for each venue. The mean percentage difference for all venues will be calculated and this will be reported alongside the 95% CI.

Research governance

Research will adhere to the Wellcome Trust Policy on Good Research Practice and the UK Policy Framework for Health and Social Care Research. Researchers also follow the principles laid out in the UK concordat to support research integrity.

Ethical considerations and informed consent

Ethics approval will be obtained from the Faculty of Science Research Ethics Committee at the University of Bristol (reference number 73621). The research team will provide the publicans with an information sheet explaining the nature, purpose and potential risks of the study. The publicans will be given sufficient time to read the information sheet, discuss the study with their colleagues, consider any implications and raise any questions with a member of the research team prior to making a decision to participate. Written informed consent will be obtained. The publicans will be informed that they are free to withdraw at any time.

Sponsorship

The University of Bristol will sponsor this study.

Safety

It is not anticipated that the study intervention will increase levels of intoxication. Publicans are responsible for the safety of patrons following their normal procedures.

Data management

All aspects of the General Data Protection Regulation, Data Protection Act 2018 and the Freedom of Information Act 2000 will be adhered to. All personal data will be treated as confidential.

Participant Identifiable Data (PID)

The University of Bristol is the data controller for this study. Hard copy publican consent forms will be stored in a locked filing cabinet and retained by the School of Experimental Psychology for a period of 10 years after study completion. Publican contact details will also be retained for 10 years if they agree to be re-contacted about future studies.

Anonymised study data

All study data, including volume sales, total number of transactions and head counts will be anonymised using a unique numeric identifier. Study data will be stored on an encrypted cloud server after study 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.

Data sharing

Anonymous study data may be shared with collaborators for the purposes of analysis and results interpretation under appropriate collaboration agreements.

Long-term data archiving

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 20 years.

Open access

At the appropriate time, the anonymous study data sheet will be locked and made open using the Open Science Framework and / or the University of Bristol Research Data Repository.

Revoked data

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

Quality control and quality assurance

The research team will be responsible for data quality.

Insurance

The University of Bristol holds appropriate liability insurance for research studies involving human participants. Further information can be found at the link below:

http://www.bristol.ac.uk/secretary/insurance/liability-insurance/#employers.

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 research team. The data will be made available for sharing via the Open Science Framework and / or University of Bristol Research Data Repository.

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Conflicts of interest

The study investigators have no known conflicts of interest to declare.

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