



*Generating and Implementing Evidence
to Improve Health for All*

STUDY PROTOCOL

Impact on beer sales of removing pints from the range of options available in licensed premises

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Abstract

Background

Smaller serving sizes of alcoholic drinks could reduce alcohol consumption across populations thereby decreasing the risk of several diseases. Removing the largest serving of wine by the glass from the range of available options in licensed premises can decrease wine sales – a proxy for consumption - but there is a lack of evidence surrounding the use of equivalent interventions for reducing consumption of other alcoholic drinks. This study will assess the impact on beer sales of removing the largest serving size of draught beer by the glass (1 pint), so that the largest serving size available becomes 2/3rds of a pint.

Methods

The study will be conducted in 10 licensed premises (pubs, bars and restaurants) in England. It will take place over three 4-weekly periods using an ABA reversal design, where A will be the non-intervention period, during which standard sizes will be served, and B the intervention period, during which the largest serving size of draught beer and cider (pint) will be removed from premises' existing range and the largest serving size available becomes 2/3pint. Where 2/3pints are not usually served, the intervention will include introducing this serving size. The primary outcome will be the daily volume of beer and cider sold, extracted from sales data.

Discussion

The results of this study will provide novel and important evidence regarding the potential to reduce alcohol consumption at population-level by modifying the range of serving sizes of beer and cider in licensed premises, with direct relevance for public health policies tackling alcohol consumption.

Background

Alcohol consumption contributes to premature mortality and preventable morbidity [1], causing approximately three million global deaths per year and accounting for 5.1% of the global burden of disease [2]. Reducing alcohol consumption across populations is a global public health priority [3].

Interventions that alter aspects of the physical environments that promote unhealthier behaviours, including alcohol consumption, have significant potential to exert effects scalable to populations [4]. Such interventions include increasing the price of alcoholic drinks, and controlling their marketing and licensing [5, 6]. Of promise are also interventions that involve changing the size of portions and containers of products that can harm health [7], including alcohol [2]. This follows from evidence showing that people consume less food when presented with smaller portions, packages, or tableware [8-10].

Recent evidence suggests that reducing the size of the servings and containers for alcohol has the potential to reduce consumption. Larger wine glasses increase the volume of wine sold, and therefore consumed, in restaurants [11]. Smaller wine glasses might reduce the amount of wine drunk in homes although the evidence for this is extremely limited [12]. Drinking wine at home from smaller bottles, compared with standard 75cl bottles, may also reduce consumption when the bottles are 50cl [13] but the impact of 37.5cl bottles is less certain [12].

Interventions that target the sizes of servings to reduce alcohol consumption can be classified broadly into three groups [14]:

- i. removing the largest serving size from existing options;
- ii. reducing the smallest serving size (either by adding a new smaller size or reducing the existing smallest size);
- iii. adding a size smaller than the largest serving size to existing options.

The limited evidence to date suggests that the third of these - adding a size smaller than the largest serving size to existing options - does not seem to impact alcohol consumption. This is supported by findings of one recent study, conducted in real-world settings, in which adding a serving size of draught beer of 2/3rds of a pint that was between the largest (1 pint) and smallest size (1/2 pint) across 13 licensed premises had no discernible effect on the volume of beer sold [15].

In contrast, removing the largest serving size from existing options has shown potential for reducing alcohol consumption. In the only study conducted in real-world settings to assess this, removing the largest serving size of wine by the glass (most often 250ml) for four weeks decreased wine sales – a proxy for consumption - across 21 licenced premises by 7.6% (95% CI -12.3%, -2.9%) [16]. The impact of this intervention on the sales, and therefore consumption, of other alcoholic drinks is unknown.

In the case of draught beer and cider in the UK, the largest and most popular serving size is the pint [17]. At 568ml, this size is considerably larger than the typical sizes for draught beer found in other countries, making it an appropriate target for intervention. For example, in the USA the largest and most popular size is 473ml [18]. In the Netherlands and Belgium, the usual serving size is 250ml, in France it is 330ml and in Germany 500ml, depending on the region and type of beer ordered [17].

Aim

The aim of the current study is to assess the impact on sales of removing the largest serving size of draught beer and cider by the glass (1 pint), so that the largest serving size available becomes 2/3rds of a pint. We hypothesise that the intervention will reduce the volume of beer and cider sold.

Methods

Study design

The study will use an ABA treatment reversal design consisting of three consecutive four-week periods, in which A represents the non-intervention periods during which usual serving sizes will be available, and B represents the intervention period during which the largest serving size of draught beer and cider (pint) will be removed from premises' existing range and the largest serving size available becomes 2/3pint. Where 2/3pints are not usually served, the intervention will include introducing this serving size.

Setting and context

The study will be conducted in pubs, bars and restaurants in England, where the sizes of servings of alcoholic drinks sold in licensed premises are subject to regulations [19]. Draught beer and cider must legally be available in at least one of two sizes [19]: pints (568ml) -which is the most popular measure [17]- and half pints (284ml). Since 2011, one-third (189ml) and two-third pints (379 ml) can also be sold, but licensed premises are not legally obliged to make these available [17, 20].

Participants

Participants will be 10 licensed premises in England.

To be eligible to take part in the study, licensed premises will need to meet the following criteria:

- i. sell a minimum of 150 pints of beer and cider on average per week;
- ii. be willing to remove the larger serving of draught beer and cider i.e. the pint and introduce 2/3pints if this serving size is not already available;
- iii. have an electronic point of sale (EPOS) till system to record daily sales of all drinks and their served sizes;
- iv. be primarily indoor, permanent establishments in a fixed location; *i.e.* not purposefully temporary or time-limited (*e.g.* pop-up), or mobile venues (*e.g.* vans).

Premises will receive £3000 (inclusive of VAT) for completing the study and providing all necessary data.

Sample size determination

Simulation--based predictive power analysis was performed based on data from a previous study assessing the impact of removing the largest serving size of wine by the glass in 21 licensed premises, using an ABA design with each period lasting four weeks [21]. The study found that the intervention resulted in an average 7.6% reduction in the daily volume of wine sold. The simulations suggest that five licensed premises would be required for the proposed study to detect this effect size on the daily volume of beer sold with a probability of 0.85 at the 0.05 significance level. Due to the model complexity [22], it was considered favourable to increase the sample size to

10 premises. To account for possible attrition, a maximum of 13 premises will be recruited.

Withdrawal of participants

Premises' leads will be informed that they are free to withdraw from the study at any time. In the event that a premises withdraws from the study during data collection, the research team will retain the ability to use all information received prior to withdrawal unless the premises requests that the data are deleted.

Intervention

Licensed premises will remove the largest serving size of draught beer and cider (1 pint) from their existing range so that the largest serving size available is 2/3rd of a pint. Where 2/3pints are not usually served, the intervention will include introducing this serving size, with proportionate pricing as far as is possible *i.e.* with a price which is linear-by-volume between the pint and half-pint sizes. If half pints and pints are not proportionately priced then, premises will be requested to prices 2/3pints in proportion to pints. Premises will be provided with the necessary glassware by the research team. Menus and signs will be updated to reflect the changes.

Within the TIPPME intervention typology for changing environments to change behaviour [23], the type of intervention used in the current study will be 'Size', and focused on the 'Product' itself, *i.e.* the alcoholic drink (as opposed to, for example, aspects of the wider environment).

Measures

Primary outcome

Daily volume (in millilitres (ml)) of all beer and cider sold (draught as well as bottled), extracted from electronic records of sales.

Secondary outcomes

The following outcomes will be extracted from electronic records of sales from each premise:

- i. Daily volume (in ml) of beer and cider available in each serving size, for example
 - 1/3 pint (189ml) draught
 - 1/2 pint (284ml) draught
 - 330ml bottle
 - 440ml can
 - 500ml bottle
 - pint (568ml) draught
 - 600ml bottle

- 5 litre (5000ml) keg/jug

- ii. Daily volume (in ml) of wine sold
- iii. Daily revenue from food, alcoholic and non-alcoholic drinks

Covariates

- i. Maximum daily local temperature
- ii. Special events (e.g. Bank Holidays, other holidays, major sporting events, etc).
- iii. Total Revenue
- iv. Day of the week
- v. Study day from start of a period
- vi. Season at start of study

Procedure

Ethics approval will be obtained from University of Cambridge Psychology Research Ethics Committee and this protocol will be pre-registered on the Open Science Framework and ISRCTN.

Premises will change their available serving sizes for draught beer and cider two times over a period of 12 weeks: once to remove pints and introduce 2/3 pints, if this serving size is not already served, and once to re-introduce pints and remove 2/3 pints, if this serving size was added during the intervention period.

Till systems will be updated as appropriate to reflect the new serving sizes.

Premises' leads will be contacted one day before each reversal to remind them of the required changes. Fidelity to the protocol will be checked by visits organised by the research team in the first days after each reversal (Appendix A).

Premises' leads and staff will be issued with a simple explanation to give to patrons who ask why serving sizes have changed: "We have been receiving requests for differently sized drinks so we are trying out some changes for a few weeks".

Premises' leads will be invited to take part in a 30-minute end-of-study interview after the final baseline period to answer questions about their experience of taking part (Appendix B). This will take place by telephone or face-to-face.

Prior to publication, results will be shared with the premises' leads by telephone or face-to-face and they will be invited to comment.

Data analysis

Primary analysis

A generalized linear mixed model (generalized additive models which can accommodate heterogeneity) will be used to predict daily volume of beer and cider sales, the primary outcome, according to study period (A vs B). Premises will be treated as a random factor and heterogeneity between premises will be modelled. The analysis included will include pre-specified covariates for day of the week, study day (number ranging from 1 to 84) and total revenue from all food and drink (as a proxy for premises busyness).

Only premises that meet the following three conditions will be included in the primary analysis:

- i) complete the study in full *i.e.* all 12 weeks
- ii) provide primary outcome data for the 12 weeks of the study

iii) adhered to the protocol for intervention implementation i.e. they pass the fidelity checks and their data did not suggest that pints were sold during Period B.

Sensitivity analyses

Four sets of sensitivity analyses will be conducted to check the robustness of the primary analysis:

1. Regression analysis, repeating the primary analysis but taking into account three additional covariates: i) the total number of special events in each period; ii) season at the start of the study (autumn or winter); iii) maximum daily local temperature.
2. Regression analysis, repeating the primary analysis but adding daily-level data from all premises, including any that violated the protocol for intervention implementation.
3. Regression analysis, repeating the primary analysis but including the two non-intervention periods as separate factor levels (i.e. using A1, B & A2 levels for the periods).
4. Regression analysis using period-level data to compare mean daily sales during period A (aggregate value for 2 four-week A period) and mean daily sales during period B (aggregate value for 1 four-week B period). Mean daily sales for each period will be calculated by adding the total volume of beer and cider sold and dividing by the number of days the premises were open during each A and B period.

Secondary analyses

For the secondary outcomes generalized linear mixed models will be used, with the distribution of the data assessed by model diagnostics dictating which model is most appropriate (e.g. Poisson regression).

The following secondary analyses will be conducted:

1. Regression analyses to predict the number of beer and cider drinks sold in each serving size according to the study Period (A vs B).
2. A regression analysis to predict the daily volume of wine sold according to the study Period (A vs B). The analysis included covariates for day of the week, study day (number ranging from 1 to 84) and total revenue from all food and drink.
3. A regression analysis to predict total revenue from all food and drink according to the study Period (A vs B). The analysis included covariates for day of the week and study day (number ranging from 1 to 84).

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 UUK concordat to support research integrity.

Ethical considerations and informed consent

Ethics approval will be obtained from the Cambridge Psychology Research Ethics Committee based at the University of Cambridge. The investigator will provide the premises' leads with an information sheet explaining the nature, purpose and risks of the study. The premises' leads will be given sufficient time to read the information, consider any implications, and raise any questions with the investigators prior to making a decision to participate. Written consent will then be obtained. The premises' leads will be informed that they are free to withdraw from the study at any time.

Sponsorship

The study will be sponsored by the University of Cambridge.

Insurance

The study will be insured by the University of Cambridge. The University of Cambridge arranges insurance cover for legal liability to pay damages for injury to volunteers participating in the study which has been caused by the University or its employees. Adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.

Safety

The premises will follow their usual safety procedures. It is possible that the intervention increases alcohol sales amongst patrons, contrary to the study hypothesis. Local licensing regulations require the licensee to abide by the terms of the license, which includes not serving alcoholic beverages to a drunk person.

Incident reporting

Incident reporting will follow the usual process for the site and University of Cambridge procedures. Incidents will be documented as soon as possible by the site manager using an incident report. The reports will be anonymised by unique study identifier and stored in a locked filing cabinet. Incidents will be followed up until resolved if possible. At the end of the study a safety report will be compiled and sent to the Principal Investigator listing all incidents. The Cambridge Psychology Research Ethics Committee will be notified of breaches as appropriate.

Data management

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

Personally Identifiable Data (PID)

The University of Cambridge is the data controller for this study. Hard copy consent forms will be stored in a locked filing cabinet for one year after study completion, after which these documents will be destroyed. PID including the premises' manager names and contact details will be stored on the Cambridge Secure Data Hosting Service (SDHS).

Anonymous study data

Electronic data will be anonymised by a unique study identifier and the key located on the hard copy consent forms.

Anonymous sales data will be provided by the sites under a Data Transfer Agreement. Expectations for the Data Transfer Agreement are set out in the remainder of this section, although terms may vary as part of the negotiation process. A unique study identifier will be given to each site (with the key held on the hard copy consent form).

Anonymous study data will be stored on University of Cambridge network drives if electronic and/or in locked filing cabinets. Computer data files will be regularly backed up on a University of Cambridge network drive.

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 anonymous data sheet) will be transferred to a designated storage facility for long-term archiving. Hard copy data will be retained in locked storage facility. Study data will be kept for a minimum of 20 years.

Collaborators may retain anonymous study data in line with the relevant collaboration agreements.

Open access

All data from this study will be made available open access on the condition that premises' leads agree to this

Revoked data

If a premises lead decides that they do not want their data used after participation they can request that the data are withdrawn. They can request this up to one year after study completion.

Quality control and quality assurance

The investigators will be responsible for data quality.

Publication policy

The findings from this study will be published in at least one scientific journal and made available open access. They will also be presented at one or more scientific meetings.

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Conflicts of interest

There are no known conflicts of interest to declare.

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Appendix A: Fidelity check protocol

Fidelity checks will take place at each site in the first days after each change is made according to the protocol (*i.e.* in the first days after a site has removed pints and introduced 2/3 pints, if this serving size is not already served, and in the first days after the pints should be re-introduced and 2/3 pints removed, if this serving size was added during the intervention period) to ensure the study protocol is being implemented correctly.

Checks will be made either during a visit by a confederate

During visits, compliance with the intervention will be checked as described below.

Removal of pints

- A. A confederate will order a pint of any beer or cider. Compliance with the intervention would require staff to inform that the largest serving size available is 2/3 of a pint and then to serve the confederate's chosen serving sizes of those available (1/2 or 2/3 pint)
- B. A confederate will observe the site for a period of 30 minutes. Compliance with the intervention would require that customers asking for a pint are informed that this size is not available and are served either 1/2 or 2/3 pints or otherwise a bottled option
- C. Printed and/or electronic menus will also be checked to ensure the pints have been removed and 2/3 pints added

Reintroduction of pints:

- A. A confederate will order a pint of any beer or cider. Compliance with the intervention would require the staff to serve a pint
- B. A confederate will observe the site for a period of 30 minutes. Compliance with the intervention would require that customers asking for a pint are served pints
- C. Printed and/or electronic menus will also be checked to ensure pint options have been reintroduced

In all cases, a premises will be considered to have failed the fidelity check if either of the criteria A or B are not satisfied. If criterion C is not satisfied, this will be recoded but will not result in a site failing the fidelity check.

If premises fail any of the checks, they will be asked to rectify the observed protocol violation before an additional fidelity check takes place within 24 hours. A premises might be asked to extend the study period to make up for days that have to be excluded from the analyses due to failed fidelity checks.

Appendix B: End of study interview

This interview schedule is designed for the premises leads who participated in 'The impact on beer sales of removing pints from the range of options available for beer in licensed premises' study. The interview will be conducted over the phone.

The interview

This conversation will last about 30 minutes. I will ask you some questions about your thoughts and experiences of taking part in the study. This interview will be tape recorded to ensure we can accurately capture your responses. Is this ok?

1. Why did you decide to take part in the study?
2. What did you think of the changes you made to your serving sizes of beer and cider?
 - a) Did you experience any practical problems with making the change? If so, what were they?
 - b) How did staff deal with the change to your serving sizes?
 - c) Did you notice any changes in the way staff dealt with customers ordering pints?
 - d) What was the reaction from customers to the removal of the pints? Did you receive any complaints?
 - e) Do you think removing pints changed how much beer and cider your customers ordered and drank?
 - f) Do you have any plans to introduce two-third pints permanently (if these were not already on offer before study)?
3. How would you feel about the sales data you provided us being made available publically as 'open data'? (This data would remain anonymous)
4. Finally, do you have any other comments about this study or the serving sizes of alcohol?
5. Would you consider taking part in a future study?

Many thanks.