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STUDY PROTOCOL

INCREASING THE RELATIVE AVAILABILITY OF ALCOHOL-FREE DRINK OPTIONS IN BARS AND PUBLIC HOUSES: A FIELD STUDY

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Background

Interventions that alter the availability of healthier and less healthy products, within the environments from which they are purchased or consumed, can facilitate healthier consumption (Allan *et al.*, 2017; Grech and Allman-Farinelli, 2015; Pechey *et al.*, 2019; Hollands *et al.*, 2019). These can be classified as Availability x Product interventions, based on the Typology of Interventions in Proximal Physical Micro-Environments (TIPPME) (Hollands *et al.*, 2017).

A Cochrane review of the impact of reducing the availability of less healthy products on their selection and consumption, reported large effects on selection and a moderate effect on consumption (Hollands *et al.*, 2019). However, concerns regarding study quality and sample size were identified and uncertainty for the reliability of these findings remains. In addition, the review only identified studies related to food products and the effectiveness of availability interventions for reducing alcohol consumption is unknown.

A recent online study found that the odds of selecting an alcohol-free drink were 71% higher when the proportion of alcohol-free drinks compared to alcoholic drink options increased from half to three-quarters, and were 37% lower when they decreased to one-quarter (Blackwell *et al.*, 2019). A subsequent online study indicated that increasing the proportion of non-alcoholic drinks available – from 25% to 50% or 75% – reduces alcohol selection and purchasing (Clarke *et al.*, 2022). While both of these studies provide initial support for availability interventions in relation to alcohol products, replication in real world environment with behavioural outcomes is required.

The development of low and alcohol-free drink options is encouraged as part of a broader range of evidence-based strategies to reduce alcohol-related harm (Anderson *et al.*, 2013). Alcohol-free drink options are often given secondary importance in restaurants and bars (e.g., listed at the back of a menu or stored in a low-level fridge). Ubiquitous alcohol marketing within drinking environments, as well as stigma around drinking alcohol-free drinks,

discourages alcohol-free drink selection and consumption (HardcastleO'connor and Breen, 2019; Davies Emma, 2018; Club Soda, 2016).

However, the market for low and alcohol-free drink alternatives is growing (The Morning Advertiser, 2019). Widening the choice available for consumers and increasing alcohol-free drink exposure could encourage their selection and shift social norms (RenoCialdini and Kallgren, 1993; Zajonc, 2001). Increasing the availability of alcohol-free alternatives provides an opportunity for licensed venues to take positive action to address licensing objectives regarding public safety and crime and disorder, broaden their offer to customers and maintain revenue (Club Soda, 2016; Licensing Act 2003 C.17). Additionally, the UK Government has pledged to increase the availability of alcohol-free and low-alcohol products by 2025 (Department of Health and Social Care, 2021), although details on what this would involve have yet to be published.

Evidence of the impact of increasing the availability of alcohol-free drink options on alcoholic and alcohol-free drink selection and consumption is required to support policy decisions in this area.

Study Aim and Hypotheses

The aim of this study is to estimate the impact of increasing the proportion (i.e., the relative availability) of draught alcohol-free beer on alcohol consumption in bars and public houses.

Hypothesis: Replacing one draught alcoholic beer with one draught alcohol-free beer lowers the volume of draught alcoholic beer sold in licensed premises.

Hypothesis: Replacing one draught alcoholic beer with one draught alcohol-free beer does not reduce the revenue from all drinks sold in licensed premises.

Study Design

A minimum of 12 and up to 16 sites (bars and public houses) in the UK will be recruited to take part in this randomised four-period crossover trial. All participating sites will perform two intervention periods (A) and two control periods (B) in a random order. A minimum of three and up to four sites will be randomised to each of four possible orders: 1) BABA; 2) BAAB; 3) ABBA; or 4) ABAB. Each period will last two weeks and therefore each site will be monitored for eight weeks in total. During the intervention condition, sites will remove one draught alcoholic beer and replace it with one draught alcohol-free beer. During the control condition, sites will have no alcohol-free beer on draught (i.e., usual practice).

Intervention

Sites will remove one draught alcoholic beer (i.e., alcoholic lager or ale) and replace it with one draught alcohol-free beer (i.e., alcohol-free lager or ale). Sites will be able to choose which draught alcoholic beer to remove and which draught alcohol-free beer to replace it with. Sites will be encouraged to replace this like-for-like (i.e., replace a draught alcoholic lager with a draught non-alcoholic lager). However, if sites have strong motivations for not wanting to replace like-for-like (i.e., sites want to replace an alcoholic ale with an alcohol-free lager) this will be permitted. All replacements throughout the study will be kept consistent, for example if an alcoholic lager is replaced by an alcohol-free lager, then this

same replacement must be used throughout the study (i.e., using the same brand and type).

The beer type (lager or ale) for both the removed alcoholic beer and the replacement alcohol-free beer will be recorded for each site and described descriptively. The brand also be recorded for the alcohol-free replacement and described descriptively.

As part of the intervention, sites will be encouraged to advertise the new draught beer in the same way as it would with any other new product (tap badges, signs behind the bar and information on menus and any apps). These practices will be recorded but not controlled.

Within the TIPPME intervention typology for changing environments to change behaviour (Hollands et al., 2017), the type of intervention proposed here is Availability and is focused on the product itself (i.e., alcohol, as opposed to aspects of the wider environment).

Study Site

This study will be administered by the School of Psychological Science at the University of Bristol, but will be conducted in bars and public houses in the UK.

Recruitment

Sites will be recruited by directly contacting publicans. We will initially use existing contacts who took part in at least one of our previous alcohol field studies (i.e., glass shape field study and / or serving size field study) and expressed an interest in taking part in future studies. Sites will be offered financial compensation of £500 for participating in this study.

Inclusion criteria for pubs and bars

- Have at least three alcoholic beers (lager or ale) on draught.
- Do not currently have any alcohol-free beers (lager or ale) on draught to ensure that the intervention (i.e., introducing alcohol-free beer on draught) is novel for all sites.
- Willing to remove one draught alcoholic beer and replace it with one draught alcohol-free beer.
- Have an electronic point of sale (EPOS) till system to record itemised sales of all drinks.
- Be willing to update the EPOS system to include ‘draught alcohol-free beer’ during intervention periods.
- Be willing to share itemised EPOS data with the research team for the duration of the study.
- Be willing to advertise the new draught beer in the same way the pub or bar would with any other new product (tap badges, signs behind the bar and information on menus and any apps).

Withdrawal of sites

Sites will be informed that they are free to withdraw from the study at any time. In the event that a site withdraws during data collection, they will not receive any financial reimbursement.

Sites will be able to withdraw complete data up to one year after the study or until the data are made open for sharing (whichever comes first) without having to give a reason.

Precision estimate

We previously conducted a field study in 24 sites in the UK to estimate the impact on alcohol consumption of serving draught alcoholic beer in straight-sided glasses compared with usual, predominantly curved glasses (Brocklebank *et al.*, 2021). This study had a similar design to the current study and found a mean difference of -35 litres in the volume of draught alcoholic beer sold between intervention and control periods (A-B). The standard deviation (SD) of this mean difference was 141 litres. Table 1 reports the 95% confidence interval (CI) of this SD for increasing values of N. Table 1 suggests that a minimum of 12 and up to 16 sites are required to have sufficient precision in the current study because it is at this point that the relationship between increasing N and increasing precision (i.e., narrower 95% CI of the SD) starts to plateau.

Table 1. Precision estimate: calculating the 95% CI of the SD

SD (litres)	N	Lower CI (litres)	Upper CI (litres)
141	6	88	346
141	8	93	288
141	10	97	258
141	12	100	240
141	14	102	228
141	16	104	219
141	18	106	212
141	20	107	206
141	22	109	202
141	24	110	198

N = the number of bars and public houses.

We consider this to be an opportunistic study providing preliminary evidence to inform future research, including more precise calculation of the likely effect size and the required sample size for future studies.

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 by computer by an independent researcher who will email a member of the research team the order allocations in separate files (one for each of the participating sites). After a site has been recruited and eligibility has been confirmed, the password-protected file relating to that enrolment number will be opened by a member of the research team and the site 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 sites are assigned to each order (Figure 1).

It is not possible to blind the research team or the participating sites to order allocation. Drinkers will however not be aware of the study and therefore will be blinded to the study hypothesis.

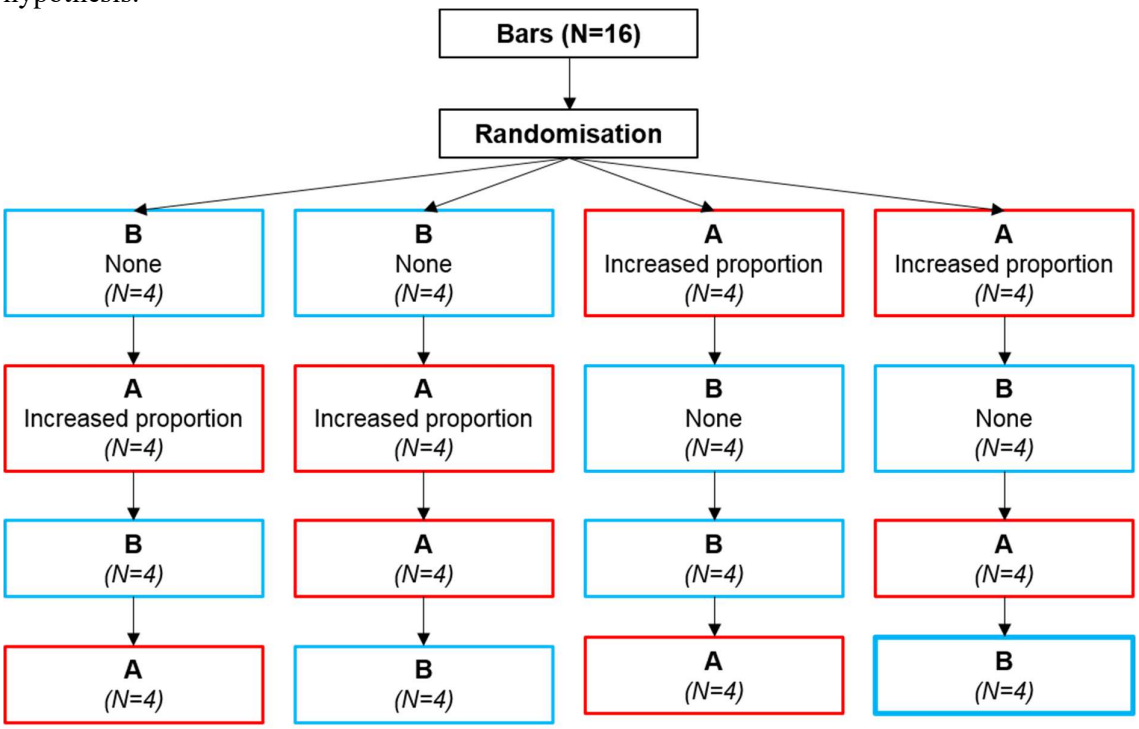

Figure 1. Random order allocation.

All participating sites will perform two intervention periods (A) and two control periods (B) in a random order. Each period will last two weeks. During the intervention condition, sites will remove one draught alcoholic beer and replace it with one draught alcohol-free beer (i.e., increased proportion). During the control condition, sites will have no alcohol-free beer on draught (i.e., none).

Measures

Primary outcome

The mean volume (in litres) of draught alcoholic beer (lager and ale combined) sold weekly. This will be an aggregated value of the two two-week A periods and the two two-week B periods, respectively, expressed as a weekly amount.

Secondary outcome

Mean weekly revenue from all drinks (in £) (i.e., alcoholic and alcohol-free drinks combined).

Tertiary outcomes

1. The mean volume (in litres) of all alcohol-free beer (i.e., lager and ale combined) sold weekly, including both draught and bottled.

2. The mean volume (in litres) of all alcoholic beer (i.e., lager and ale combined) sold weekly, including both draught and bottled.
3. The mean volume (in litres) of bottled alcoholic beer (i.e., lager and ale combined) sold weekly.
4. The mean volume (in litres) of all alcoholic drinks sold weekly, excluding alcoholic beer.
5. The mean volume (in litres) of all alcohol-free drinks sold weekly, excluding alcohol-free beer and soft drinks.
6. The mean number of soft drinks sold weekly.

All outcomes will be aggregated values of the two two-week A periods and the two two-week B periods, respectively, expressed as a weekly amount.

Additional measures

1. The total number of non-study drinks (i.e., not including any draught alcohol-free beer sold) sold weekly will be used as a proxy measure of site busyness.
2. The total number of special events during each period that were likely to have increased sales. Special events will include any event held by the site that is outside of the normal schedule for that site. Therefore, this will exclude any regular events (i.e., weekly, fortnightly and monthly events), but will include any public holidays or sporting events.
3. The total number of alcohol-free drink options at baseline (i.e., during usual practice).

Procedures

This protocol will be pre-registered on the Open Science Framework.

We anticipate that all data will be collected between July 2022 and 21st November 2022 (therefore, data collection at each site will commence before the 25th Sept 2022). If data collection needs to continue past this time point, the study will be paused between 21st November 2022 and February 1st 2023 to allow for the FIFA world cup, Christmas period and Dry January period.

Written consent will be obtained for each site prior to data collection.

Sites will change the proportion of draught alcohol-free beer two to four times over a period of eight weeks depending on random order allocation (Figure 1). During each intervention period EPOS systems will be updated as appropriate to reflect the new draught alcohol-free beer option. Site leads will be provided with a schedule and contacted 24-hours before each reversal to remind them of the required changes. At the end of the study, all data will be sent electronically by each site to the research team. Once the data has been received by the research team the site will receive reimbursement.

During both study periods sites will still be able to sell alcohol-free beer in bottles or cans. Prior to publication, results will be shared with the site leads by email or face-to-face and they will be invited to comment.

Fidelity Checks

Fidelity to the protocol will be checked by site visits organised by the research team in the first few days after each reversal.

A site will be considered to have failed the fidelity check if any of the following criteria are **not** satisfied:

Intervention (A) periods

- One draught alcoholic beer has been removed and replaced with one draught alcohol-free beer.
- A confederate for the research team will order a pint / half pint of draught alcohol-free beer. Compliance with the intervention would require bar staff to serve a pint / half pint of draught alcohol-free beer.
- A confederate will observe the site for a period of 30 minutes. Compliance with the intervention would require that customers ordering a pint / half pint of draught alcohol-free beer are being served a pint / half pint of draught-alcohol free beer.

Any promotion of the draught alcohol-free beer through tap badges, information on menus and apps, and signs behind the bar, will be recorded. However, a lack of any of these promotions will **not** result in a fidelity check fail.

Control (B) periods

- There are no draught alcohol-free beers being sold.
- A confederate will order a pint / half pint of draught alcohol-free beer. Compliance with the intervention would require bar staff not to serve a pint / half pint of draught alcohol-free beer.
- A confederate will observe the site for a period of 30 minutes. Compliance with the intervention would require that customers ordering a pint / half pint of draught alcohol-free beer are not being served a pint / half pint of draught-alcohol free beer.

If a site fails 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 site 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. However, sites will not be excluded if they fail ≥1 attention check and will still receive full reimbursement.

Site leads and staff will issue a simple explanation to patrons who ask why the draught beer options have changed: “We have been receiving requests for alcohol-free beer on draught, so we are trying out some changes for a few months”.

Site leads will be invited to take part in a 30-minute end-of-study interview after the final study period to answer questions about their experience of taking part and for any verbal feedback they receive from patrons during the study period. This will take place by telephone or face-to-face.

Statistical Plan

Primary outcome

Primary analysis: For the primary analysis of the primary outcome the mean difference will be estimated according to whether alcohol-free draught was available or not available. This will be done by comparing the mean volume (in litres) of draught alcoholic beer (lager and ale combined) sold weekly between the A periods and the B periods using a mixed effects model for repeated measures, or similar (i.e., availability of alcohol-free draught beer compared to no availability of alcohol-free draught beer).

Unadjusted mean differences with 95% CIs, t statistic and p values will be reported. A Cohen's d effect size will also be calculated.

Secondary analysis: For the secondary analysis of the primary outcome a mixed effects model for repeated measures, or similar will be used to compare the mean volume (in litres) of draught alcoholic beer (i.e., lager and ale combined) sold weekly in the A periods and the mean weekly volume of sales in the B periods, with adjustment for any order effect (using study arm [i.e., the four sequences of: BABA; BAAB; ABBA; ABAB]). Adjustment will also be made for: special event (the total number across study periods); season (spring, summer, autumn or winter) that the site commenced the study in; and busyness (total number of non-study drinks sold weekly).

Two interaction terms – glass shape x season and glass shape x order will also be added to the model, but since such effects seems implausible, and would carry low power, significance levels of $p > 0.001$ will be removed from the model.

Adjusted mean differences with 95% CIs, t statistic and p values will be reported. A Cohen's d effect size will also be calculated. All interaction terms will be reported.

Secondary outcome

The secondary outcome will be analysed in the same way as the primary outcome. The mean difference and 95% CI for the mean difference and exact p-values will be presented. A Bayes factor will also be calculated to assess evidence for no difference between the study periods.

Tertiary outcomes

All tertiary outcomes will be reported descriptively between study periods. The mean difference and 95% CI for the mean difference will be presented

Sensitivity analysis

Per-protocol analyses, for the primary and secondary analyses of the primary outcome, will be repeated after excluding any sites that fail at least one fidelity check.

The primary and secondary analysis of the primary outcome will also be repeated including only those sites that replaced their alcoholic beer taps like-for-like (i.e., only those sites that replaced an alcoholic lager with an alcohol-free lager or replaced an alcoholic ale with an

alcohol-free).

A full statistical analysis plan will be pre-registered on the Open Science Framework prior to data inspection.

Ethical Considerations and Informed Consent

Ethics approval has been obtained from the School of Psychological Science Research Ethics Committee at the University of Bristol (Approval Code: 12005). The study will be conducted according to the revised Declaration of Helsinki (2013) and the 1996 ICH Guidelines for Good Clinical Practice E6(R2). The investigator will explain the nature, purpose and risks of the study to each site lead (manager / publican / owner). The site lead will receive the information sheet in advance of the study session. There will be no time restriction on how long site leads take to respond, with the exception that site leads who respond after all study places have been filled will not be offered a place on the study. Therefore, site 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. Site leads will be informed that they are free to withdraw at any time.

Consent will be obtained and stored electronically in a password protected folder on a secured University of Bristol network drive.

Safety

It is not anticipated that the study intervention (replacing an alcoholic draught alcohol beer with an alcohol-free draught beer) 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 (GDPR) and the Data Protection Act (DPA) 2018 will be adhered to.

Anonymised study data

Case report forms (CRFs), including fidelity check CRFs, will be anonymised by a unique numeric identifier (Study ID). CRFs will be stored electronically on a secured University of Bristol network drive. All data requested on the CRF will be recorded in a data spreadsheet. All missing data will be explained. Once data from CRFs have been inputted into the data spreadsheet they will undergo a reliability check (20% check by independent researcher). If an error rate greater than 1% is obtained the data will be re-inputted in full and assessed again. After the study data has been made open, all CRFs will be electronically destroyed.

At the end of the study, all anonymised electronic study documents will be transferred to a designated University of Bristol Research Data Storage Facility for long-term archiving. Study data (the data spreadsheet) will be kept for a minimum of 15 years.

An identity log (linking each bar or pub to its data) will be stored electronically in a password protected folder on a secured University of Bristol network drive. This will be kept for one year after study completion or until data are made open (whichever comes first).

Contact details

Contact details for each pub or bar (bar name, email address, telephone number) and name of primary contact(s) at site will be stored electronically on a secured University of Bristol network drive, separately from the anonymised study data, and kept confidential. These will be kept for one year after study completion or until data are made open (whichever comes first), after which these documents will be electronically destroyed.

Consent forms will be retained electronically on a secured University of Bristol network drive by the School of Psychological Science for a period of 10 years after study completion.

Revoked data

If a pub or bar 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).

Data sharing

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

Open access

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

Quality control and quality assurance

The research team will be responsible for data quality and input monitoring (as stated above).

Insurance

This study will be sponsored by the University of Bristol. The University of Bristol has Public Liability Insurance to cover the liability of the University to research participants. In the event that something goes wrong and someone is harmed during the research study there are no special compensation arrangements. If someone is harmed and this is due to someone's negligence then they may have grounds for a legal action for compensation against the 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

There are no known conflicts of interest to declare.

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