



MRC Integrative
Epidemiology
Unit



University of
BRISTOL

School of Psychological Science
12a Priory Road
Bristol BS8 1TU
United Kingdom

kd16662@bristol.ac.uk

www.bristol.ac.uk

STATISTICAL ANALYSIS PLAN

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

Katie De-loyde, Jennifer Ferrar, Lilli Waples, Mark Pilling, Joe Matthews, Olivia Pillinger, Natasha Clarke, Olivia M Maynard, Tiffany Wood, Carly Heath, Gareth J Hollands, Theresa M Marteau, Marcus R Munafò, Angela Attwood

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).

Study 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.

Data

All data received from sites will be double entered into Excel. Any discrepancies between data entry will be audited by the lead researcher to establish an error rate. If the error rate is > 5% between the two data entries, the data will be re-calculated by the lead researcher and a decision will be made on which data point will be used. Data will only be considered by the research team in period blocks (i.e., for each site, the data will be summarised for periods 1,

2, 3 and 4 separately), and will only be available on a period basis (i.e., even if the site provides daily data, the data will be aggregated into periods by the research team).

Outcomes

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 A periods and the two B periods, respectively, expressed as a weekly amount (i.e., the total amount for the two A periods, divided by 4 to give a weekly average, and the total amount for the two B periods, divided by 4 to give a weekly average).

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 A periods and the two 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).
4. The total number of fidelity checks passed and failed by each site.

Outliers

Any outliers for each outcome will be identified using range checks, scatter plots and histograms. True outliers will be defined as any value where the median absolute deviation exceeds 3. Any true outliers will be included in the primary and secondary analysis but, if deemed necessary, a sensitivity analysis will be completed without any true outliers to compare results.

Missing data

Data that are not applicable will be coded as -8888. Data that are missing due to an administrative or other error will be coded as -9999.

Missing data checks

If an excessive amount of missing data (defined as >10%) is identified for any outcome variable, the research team will be notified so that checks can be made. If there is a sufficient amount of missing data for a variable, then it will be considered for exclusion.

We anticipate that all primary and secondary outcomes will be complete, but any data which has missing fields will be analysed on a complete case basis.

Outcome analysis

All analysis will be done in either IBM SPSS version 29 or a similar software. Analyses will be coded in syntax, and this will be made available on data.bris repository together with the study data set upon any manuscript acceptance.

Primary outcome (the aggregated volume of draught alcohol-free beer for the two two-week periods, expressed as a weekly amount)

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 as per the hypothesis).

Unadjusted mean differences with 95% confidence intervals (CI), 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 – alcohol-free availability x season and alcohol-free availability x order will also be added to the model, but since such effects seem implausible, and would afford low statistical power, interaction terms with p-values > 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 aggregated revenue from all drinks for the two two-week periods, expressed as a weekly amount)

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 as per the hypothesis.

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 analyses

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 ale).

Model types

The type of model used for each analysis, will be based on the scale and distribution of each outcome. Non-linear models will be considered, depending on the distribution of model residuals.