behaviour change by design

Generating and Implementing Evidence to Improve Health for All

ANALYSIS PLAN

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

Laura A Brocklebank*, Anna K M Blackwell, Olivia M Maynard, Theresa M Marteau, Gareth J Hollands, Paul C Fletcher, Angela S Attwood, Katie De-loyde, Richard Morris, Mark Pilling, Rachel Pechey, Marcus R Munafò

Study design

A randomised multi-period crossover trial where all participating venues complete two intervention periods (A) and two control periods (B) in a random order: 1) BABA; 2) BAAB; 3) ABBA; or 4) ABAB.

Intervention period (A): lager, ale and cider will be served in straight-sided pint and half pint glasses for two weeks.

Control period (B): lager, ale and cider will be served in the venue's usual pint and half pint glasses for two weeks (i.e., usual practice).

Research aim

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 (collectively referred to as venues).

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.

Outcomes

Primary outcome

The mean volume (in litres) of draught lager, ale and cider (combined) sold weekly.

Secondary outcomes

1. The mean volume (in litres) of lager sold weekly.
2. The mean volume (in litres) of ale sold weekly.

3. The mean volume (in litres) of cider sold weekly.
4. The mean number of bottles of beer sold weekly.
5. The mean volume (in litres) of wine sold weekly.
6. The mean volume (in litres) of spirits sold weekly.
7. The mean number of soft drinks sold weekly.
8. The mean number of alcohol-free drinks (excluding soft drinks) sold weekly.
9. The mean volume (in litres) of all alcoholic drinks sold weekly.

Additional measures

- The total number of daily and weekly transactions during each period (for both food and drink combined).

- Head count, collected once for each study period (so 4 times in total across the study for each venue).

- Special promotions and event (recorded as: no event, minor event or major event) (collected once for each study period [4 times in total]).

- Degree of curvature of the venue's usual pint glasses (i.e., the glasses that were used during the control periods), calculated as the difference (in mm) between the halfway point in terms of height and the halfway point in terms of volume (for example, this difference is 0 mm for a straight-sided glass). A mean will be calculated for each venue and will be weighted by the proportion of total pint glasses made up by each glass type.

Fidelity check

A fidelity check (to check if the correct glass shape was being used) was conducted once for each study period (so 4 times in total across the study for each venue).

Data sharing

A clean dataset will be sent directly to the researcher completing the data analysis at the end of the study in an Excel spreadsheet. A data dictionary will also be sent which includes all coding and ranges which exactly matches the dataset.

Recoding

Calculate the mean weekly sales for straight-sided glasses (A periods combined).

Calculate the mean weekly sales for standard (the venue's usual) glasses (B periods combined).

Calculate the difference between the mean weekly sales in the B periods and the mean weekly sales in the A periods.

Outliers

Any outliers for the outcomes will be identified using range checks, scatter plots and histograms. If any outliers are identified (defined by any values where the median absolute deviation exceeds 3)[1] further checks will be performed by the research team to ensure they are not the result of data entry errors.

Any true outliers (as defined above) will be included in the primary 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 -888. Data that are missing due to an administrative or other error will be coded as -999.

Missing data checks

If an excessive amount of missing data (>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, as they are collated on a weekly basis. Where further exploratory analysis of daily data are concerned, we will analyse complete cases.

Violations of normality

It is expected that the primary and secondary outcomes of volume of sales and number of sales would follow a Normal distribution in the underlying population, and parametric analyses will be carried out accordingly. Nevertheless, whether the study data appears to follow a Normal distribution or not, will be assessed using normality plots on residuals from the final models specified below.

If there is any indication of a strong departure from Normality for any of the outcomes, the p-value and 95% confidence interval (CI) will be calculated using the bootstrap method with bias correction.

If any outcome shows strong evidence of a positively skewed distribution, a transformation to another scale will be considered.

Descriptive statistics

A CONSORT flow chart will be constructed to show the numbers of venues assessed for eligibility, recruited, randomised, followed up and analysed.

All raw outcome data and additional data will be reported in tables with two columns comparing the mean in the A periods and the mean in the B periods (i.e., between the two glass shape conditions). Percentages will be reported for categorical variables, and the mean and SD for continuous variables.

The mean difference (alongside the SD of the mean difference, and 95% confidence interval) in volume of sales between the A periods and the B periods will also be reported.

We will also report the percentage difference in volume of sales in the A periods and the volume of sales in the B periods. The mean percentage difference for all venues will be calculated and this will be reported alongside the 95% CI.

Outcome analysis

All analysis will be done in either IBM SPSS version 24 or R v3.6. Analysis will be coded in syntax and this will be added in an Appendix after the analysis is complete.

Primary outcome

Primary analysis

For the primary analysis of the primary outcome the mean weekly volume of sales in the A period and the mean weekly volume of sales in the B period (i.e., comparing glass shape) will be compared using a paired-samples t-test. The dependent variable will be mean weekly volume of sales and the independent variable will be study period (i.e., glass shape).

Secondary analysis

For the secondary analysis of the primary outcome a general linear model will be used to compare the mean weekly volume of sales in the A period and the mean weekly volume of sales in the B period (i.e., comparing glass shape), after 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 (no event, minor event or major event) in each period (4 special events entered as 4 separate variables); season (spring, summer, autumn or winter) that the venue commenced the study in; and head count in each period (4 head counts entered as 4 separate variables).

A term representing the carryover effect (study period [glass shape] x order interaction) will be added to the model, but since such an effect seems implausible, and would carry low power, significance levels of 1% will be adopted – this would then lead to between-venue analysis to appraise the effect of straight-sided versus usual (curved) glasses.

We will also investigate possible interactions between period, month and treatment, using a similar approach.

Tertiary analysis

For sites which provide aggregate data at the day level, regression analyses will predict daily volume of sales from glass shape (modelled using dummy variables, with the venues usual glasses being the reference group). Analyses will include study sequence (study arm) and study period (i.e., glass shape), overall sales in the venue each day, temperature at 5pm (the local temperature recorded by the Met Office. This will be collated and added to the main database by the lead research LB), and will require dummy variables indicating the day of the week, as covariates.

Heteroscedasticity will be examined, to establish if both the mean and variance of volume of sales should be modelled. First a regression modelling only the mean will be fitted (homoscedastic), as usual. Then the residuals will be examined to see if there are changes to the variance by different factors. Terms for modelling the variance will then be added to the regression model (heteroscedastic). Site will be treated as a random factor.

The mean difference and 95% CI for the mean difference and p-values will be presented for all models. A Cohen's d effect size will also be calculated.

Secondary outcomes

All 9 of the secondary outcomes will be primarily analysed by estimating the mean difference according to glass shape (with 95% confidence interval) and presenting the exact p-value from a paired-samples t-test, where the dependent variable is the secondary outcome and the independent variable will be study period (i.e., glass shape).

For the secondary analysis of the secondary outcomes general linear models will be used to compare the secondary outcomes between the two study periods (i.e., comparing glass shape), after 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 (no event, minor event or major event) in each period (4 special events entered as 4 separate variables); season (spring, summer, autumn or winter) that the venue commenced the study in; and head count in each period (4 head counts entered as 4 separate variables).

A term representing the carryover effect (study period [glass shape] x order interaction) will be added to the model, but since such an effect seems implausible, and would carry low power, significance levels of 1% will be adopted – this would then lead to between-venue analysis to appraise the effect of straight-sided versus usual (curved) glasses.

The mean difference and 95% CI for the mean difference and exact p-values will be presented for all models. A Cohen's d effect size will also be calculated.

Per-protocol analysis

A per-protocol analysis will be repeated for the primary and secondary analysis of the primary outcome which will exclude any venue that failed at least one fidelity check.

Sensitivity analysis

A sensitively analysis will be completed for the primary and secondary analysis of the primary outcome which will stratify by bar type (NUS [National Union of Students] bar and not NUS bar).

Exploratory analysis

As an exploratory analysis we will fit an interaction term (study period [glass shape] x weighted degree of curvature of the venues usual glass) to the primary outcome model (without other adjustments).

This will allow us to explore whether pubs with more curved usual glasses differ in the primary outcome from straight-sided glasses to a greater extent than pubs with less curved usual glasses. Since this is exploratory no formal statistics will be reported.

References

1. Christophe Leys, C.L., Olivier Klein, Philippe Bernard, Laurent Licata, *Detecting outliers: Do not use standard deviation around the mean, use absolute deviation around the median.* Journal of Experimental Social Psychology, 2013. **49**(4): p. Pages 764-766.