behaviour change by design

Generating and Implementing Evidence to Improve Health for All

ANALYSIS PLAN

Size and shape of plates and size of wine glasses and bottles: impact on selection of food and alcohol

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Sample size

This study was terminated early, on the 17th March, due to the COVID-19 pandemic. We are analysing the data collected which is 50% (n=140) of the intended total. Due to potential changes in people's consumption behaviours post-COVID-19, any additional data will be collected as part of a new study. The analysis plan will not change because of this decision, however an updated power calculation has been conducted and it is anticipated that this reduced sample size will have 65% power. Although this level of statistical power is sub-optimal, our original sample size calculation was very conservative, derived to detect a small-sized effect (d=0.2), even though the most recent meta-analyses of tableware size and selection (Holden et al., 2016; Hollands et al., 2015) both estimate a moderate-sized effect (d=0.5) of tableware size on selection of food.

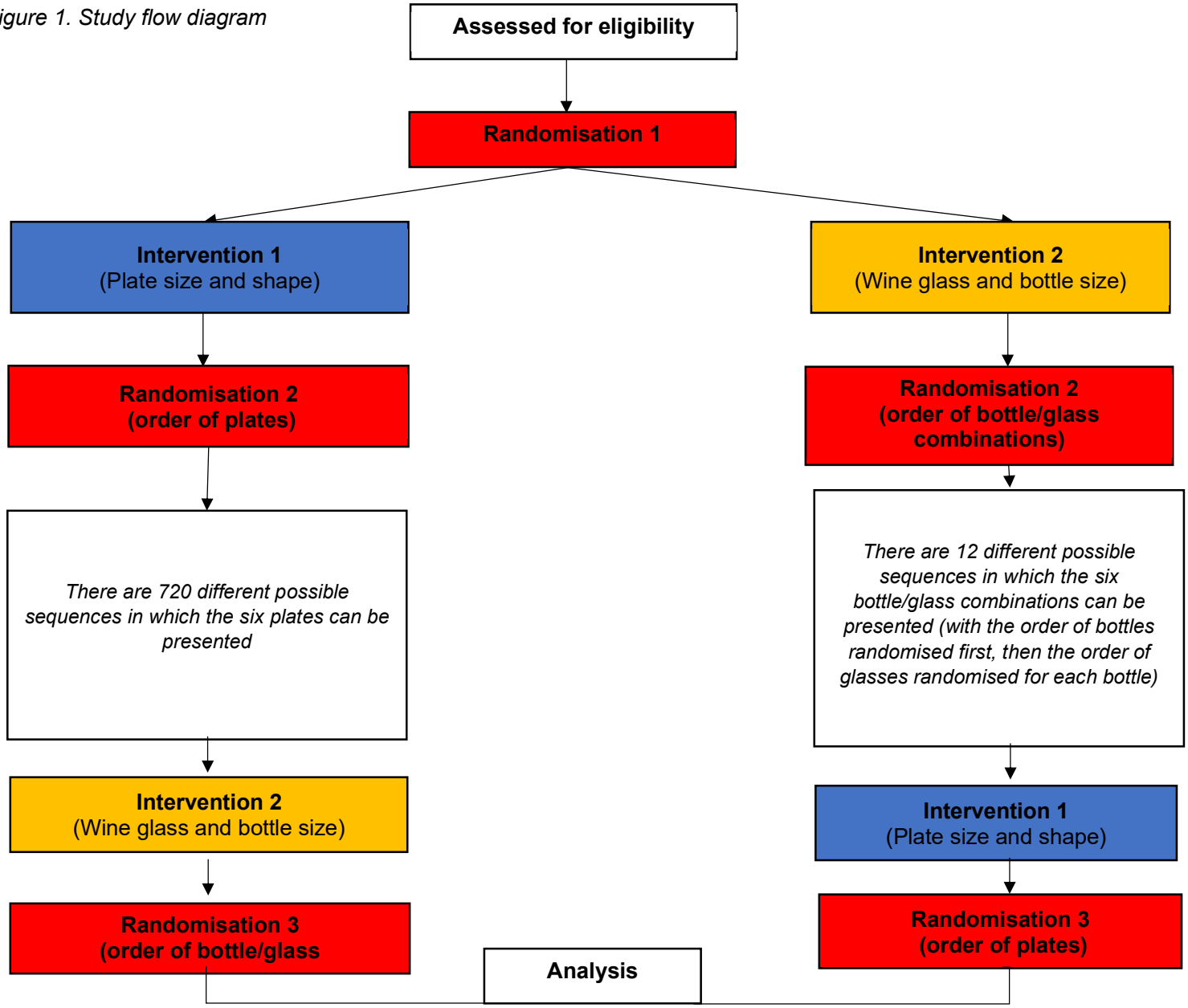
Study design

This study involves two interventions: one for food (intervention 1) and one for drink (intervention 2):

1) A within-subjects factorial design with six conditions: 3 plate sizes (small; medium; large) x 2 plate shapes (circular; square). Participants will be randomised to the order of plates onto which they will self-serve food, determined by simple randomisation (Figure 1).

2) A within-subjects factorial design with six conditions: 3 glass sizes (29cl; 35cl; 45cl) x 2 bottle sizes (50cl; 75cl). Participants will be randomised to the order in which they free-pour from each of the bottles into each of the glasses, determined by simple randomisation (Figure 1).

Figure 1. Study flow diagram



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Hypothesis

Intervention 1

Primary hypothesis: As plates increase in size, an increasing amount of food is self-served on to them.

Secondary hypothesis: Plate shape will change the amount of food self-served, but there is insufficient evidence for this to suggest a direction.[1]

Intervention 2

Primary hypothesis: As wine glasses increase in size, an increasing amount of wine is self-poured.

Secondary hypotheses:

I. More wine is self-poured from larger bottles compared with smaller bottles.

II. There will be an interaction between bottle size and glass size, such that the effect will be greatest when the largest glass is used with the largest bottle.

Outcomes

Primary outcomes

Intervention 1: amount of food (in grams) self-served

Intervention 2: amount of wine (in millilitres) self-poured
(this outcome is measured in grams, so to covert from grams to millilitres, values will be multiplied by 0.98 - http://web2.slc.qc.ca/jmc/w05/Wine/results.htm)

Filler questions (after each serve/pour)

Intervention 1

a) How visually appealing do you think this food is on this plate?
b) Would you like to eat from this plate?
c) How easy was it to serve from this bowl onto this plate?

Intervention 2

a) How visually appealing is this wine in this glass?
b) Would you like to drink from this glass?
c) How easy was it to pour from the bottle into this glass?

Demographics

Demographics: age; sex; measured height and weight, education.

[1] This hypothesis is not in the registered protocol (secondary hypothesis for intervention 1). This was added to the SAP for clarity, to specify that we do expect a difference between the plate shapes but there is insufficient evidence to suggest a direction.

Debrief questions

1. Please use the space below to briefly tell us what you think the study was about
2. Are there any additional comments about this study which you would like to add?

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 both the primary outcomes will be complete.

Violations of normality

It is expected that the primary outcomes 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, modelling assumptions will be assessed using normality plots on the residuals from the final models specified below.

If there is any indication of a strong departure from Normality for the residual plots 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 or a non-Normal regression will be considered.

Descriptive statistics

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

Intervention 1

All raw outcome data and appropriate additional measures will be reported in tables with six columns (plate size x 3 and plate shape x 2). Percentages will be reported for categorical variables, and the mean and SD for continuous variables. See example Table 1 below.

Intervention 2

All raw outcome data and appropriate additional measures will be reported in tables with six columns (glass size x 3 and bottle size x 2).). Percentages will be reported for categorical variables, and the mean and SD for continuous variables. See example Table 1 below.

Example Table 1:

Circular plate			**Square plate**		
Small plate	Medium plate	Large plate	Small plate	Medium plate	Large plate

Outcome analysis

All analysis will be done in IBM SPSS version 24 or similar. Analysis will be coded in syntax and this will be added in a repository after the analysis is complete.

Primary analysis

Intervention 1

Intervention 1 will involve a 3 x 2 repeated measures general linear mixed model. The dependent variable will be the amount of food (in grams) self-served, and there will be two independent fixed factors: 1) plate size (small; medium; large) and 2) plate shape (circular; square). Repeated measures analysis of variance will be used, so that the effects of any plate size (i.e. umbrella p-value) and shape are estimated within participants.

The initial model will include the two main effects of plate size and plate shape respectively (i.e. there will be two estimates for the effect of plate size against a reference category, and one estimate for the effect of plate shape against a reference category) and the 2-way interaction term between them (plate size*plate shape). No interaction is expected a priori, so unless the interaction term provides clear evidence of significance (which we define as $p < 0.01$), it will be dropped in favour of a model which includes only the two main effects.

Each main effect will be reported as a difference in means, against a reference group, with 95% CIs, test statistic and p-values. An effect size (Cohen d) will also be calculated and presented alongside 95% CI of the effect size. The large plate size will be used as the reference category for plate size, and circular for plate shape. Reporting these two main effects will address both the primary and secondary hypothesis for intervention 1.

If there is clear evidence of a 2-way interaction in the model above, between plate size and plate shape ($p < 0.01$), we will use the model including the main effects and interaction term to explore the effect of plate size on plate shape using effect plots: this model will be exploratory, and will be used to estimate effects (with 95% CI) of plate size for each plate shape. A F statistic and *p*-value will be reported for the interaction term.

To further address the study's main hypothesis, we will fit a second model where plate size is declared as a continuous covariate (coded as 1, 2 and 3) rather than a 3-level fixed factor, to assess the linear increase in food amount with increasing plate size

Intervention 2

Intervention 2 will involve a 3 x 2 repeated measures general linear model. The dependent variable will be the amount of wine (in millilitres) self-poured, and there will be two independent fixed factors: 1) glass size (29cl; 35cl; 45cl) and 2) bottle size (50cl; 75cl). Repeated measures analysis of variance will be used, so that effects of plate size and shape are estimated within participants.

The initial model will include the two main effects of glass size and bottle size respectively (i.e. there will be two estimates for the effect of glass size against a reference category, and one estimate for the effect of bottle size against a reference category), and the 2-way interaction term between them (glass size*bottle size). Unless the interaction term provides clear evidence of significance (which we define as $p < 0.01$), it will be dropped in favour of a model which includes only the two main effects.

Each main effect will be reported as a difference in means with 95% CIs, test statistics and p-values. An effect size (Cohen d) will also be calculated and presented alongside 95% CI of the effect size. 45cl glass size will be used as the reference category for glass size, and 75cl for bottle size. Reporting these two main effects will address the primary hypothesis and secondary hypothesis I for intervention 2.

If there is clear evidence of a 2-way interaction in the model above, between glass size and bottle size ($p < 0.01$), we will use the model including the main effects and interaction term to explore the effect of glass size on bottle size: this model will be used to estimate effects (with 95% CI) of glass size for each bottle size. A F statistic and p-value will be reported for the interaction term. Reporting the results of this interaction will address hypothesis II for intervention 2.

Exploratory analysis

A table will be displayed which shows the number of times each intervention appeared in each position in the order (example Table 2 below).

Example Table 2: Numbers of times the intervention appeared in each position in the order.

		Position in order					
		1st	2nd	3rd	4th	5th	6th
Square plate	Small plate						
	Medium plate						
	Large plate						
Round plate	Small plate						
	Medium plate						
	Large plate						

It is expected that the descriptives from Example Table 2 will be balanced between conditions in each intervention, but as an exploratory analysis a cluster variable will be added to the intervention 2 model, as a random effect, which will represent the 12 study orders (Figure 1). This would not be possible for intervention 1 due to the increased number of orders (Figure 1).

This will be exploratory only, and large standard errors, or large variance inflation factors will result in the termination of this analysis.

Sensitivity analysis 1

A sensitivity analysis of the primary analysis for both interventions will be repeated, excluding those participants that guessed the true nature of the study during the debrief questions.

Sensitivity analysis 2

A sensitivity analysis of the primary analysis for both interventions will be repeated, excluding those participants that were deemed by the researcher to not follow the instructions correctly (i.e. they served the food as a side dish rather than a main meal, or they specifically said they tried to serve the same amount of food and/or wine each time).

Additional measures

All additional measures (demographics and debrief questions) listed above will be reported descriptively only.

References

1. Christophe Leys CL, 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):Pages 764-6.