Leafleting Effectiveness Survey (LES)

Study Design and Power Consideration

By Eric Roberts, June 2017

1. Study Design

Because the motivation behind this study is to quantify the effect of an intervention, we will use a pre-test/post-test design. For this design, each subject is evaluated both before and after the intervention, effectively serving as its own control. As each subject's covariates are identical both before and after the intervention, comparison of pre-test and post-test outcomes becomes relatively straightforward.

We propose that roughly equal numbers of subjects receive each of two leaflets promoting veganism (that is, we will have two intervention arms). While the main question is whether leaflets in general have an effect, it is of interest to the researchers to compare effects of the two different leaflets as well. The analysis (random-effects modeling described Section 3) will account for the existence of two interventions and enable us to generate a "combined effect" estimate. For simplicity, the power considerations (Section 4) will focus on this combined effect estimate.

For this design, the potential confounder is time; that is, if students are rapidly becoming vegan independently of the leaflets, this effect could be misattributed to the intervention. This is the argument for a separate control group, which would undergo the same pre-test and post-test measurements as the treatment groups but would receive a spurious intervention (that is, a leaflet unrelated to veganism) in between.

In our previous experience, the effect of the genuine intervention is generally large enough so that temporal confounding is not a serious possibility. However, we recognize that the audiences for the study still may desire a separate control group, so one is included in the present plan.

2. Outcome Variables

Both pre-test and post-test surveys will include diet frequency questions asking subjects to quantify their consumption of various foods during the previous month, with response options presented as Likert scales. To maximize both statistical validity and measurement reliability, outcomes will be analyzed as binary variables. This is to say that outcomes will be expressed as the percent of subjects consuming non-vegan foods less than a pre-selected cut-point (e.g. less than once per week or never). When applicable, comparisons between percentages (e.g. pre-test versus post-test results) will be formulated as odds ratios.

In practice, we will have the opportunity to explore the results using a variety of cut-points. To avoid the perception of fishing for results, however, it is helpful to declare the intended cut-point prior to the onset of data collection. For this purpose, our intended cut-point will be less than once per week or never for the following groups of foods:

- Any non-vegan food
- Beef
- Any non-vegan food except fish

3. Statistical Analysis

As noted above, there will be two non-control arms in our design to enable us to compare the effects of two different leaflets. For each of these, standard logistic regression will be employed to quantify the effect sizes as odds ratios with associated 95%-confidence intervals. For comparison, an identical procedure will be conducted for the control group.

The primary motivating question, however, is whether leaflets in general have an effect; this means that it will be helpful to analyze the data when pooling together subjects from both treatment arms. To maintain statistical validity in this setting, we will make use of random effects logistic regression modeling for this purpose.

4. Power Considerations

The number of subjects required for the treatment arms depends on quantities described in the table below.

Quantity	What this is	Reason this is important
Pre-test probability	How common the outcome is at baseline (that is, prior to the intervention)	The more rare a phenomenon, the more subjects needed to quantify its frequency, or changes in its frequency due to the intervention
Expected odds ratio	How much of an effect the intervention is anticipated to have on the outcome	Small effects require more subjects to observe compared to large effects

Because of previous research conducted by Vegan Outreach related to pay-per-read interventions, we have a pretty good idea what each of these quantities will be. Therefore we have used these quantities (second and third columns, below) in simulation studies to determine the sample sizes we will need, with the following results.

Food avoided (never or less than once per week)	Pre-test probability (based on PPR)	Expected odds ratio (based on PPR)	Number of respondents for 80% power	Number of leaflets to distribute assuming 5% completion rate
Any non-vegan food	2.5 %	1.5	3,190	63,800
Beef	37.5 %	1.6	300	6,000
Any non-vegan food except fish	2.9 %	1.7	1,540	30,800

Finally, we consider the number of subjects for inclusion in the control group. Because control subjects are particularly expensive (that is, data cannot be collected as part of ongoing leafleting activities), we anticipate that proving the null effect to be different from the treatment effect will lie beyond the budget of this project; therefore we will only seek to demonstrate that the treatment effect for the control group will be statistically similar to zero (odds ratio similar to 1.0).

Because of this, our goal is no longer the avoidance of Type I error, and the standard logic of power analysis does not apply. Instead we will aim to enroll 500 control subjects (requiring the distribution of approximately 10,000 control booklets). Assuming an effect size of 1.0, we can therefore anticipate that our 95%-confidence intervals will be similar to the following:

Food avoided (never or less than once per week)	Pre-test probability (based on PPR)	Expected odds ratio (based on PPR)	Approximate 95%-confidence intervals
Any non-vegan food	2.5 %	1.0	0.4 - 2.2
Beef	37.5 %	1.0	0.8 - 1.3
Any non-vegan food except fish	2.9 %	1.0	0.5 - 2.1