FLICC pilot randomised controlled trial: statistical analysis plan

8th July 2015

Introduction

This document details the statistical analyses that will be conducted on data collected for the FLICC pilot RCT. It builds on the protocol for the study, published in *BMC Pilot and Feasibility Studies* in July 2015. It provides dummy tables for display of the results. This plan does not include analysis of data collected for the process evaluation (semi-structured interviews and web analytics), which will be reported in a separate paper.

Study objectives

The goal of this pilot RCT is to assess the feasibility of a full RCT to measure the effectiveness of an intervention designed to help people use traffic light food labels to purchase healthier ready meals and pizzas. To achieve this goal, the pilot RCT is designed to meet the following objectives:

1. To obtain reliable estimates regarding recruitment, retention and data completion.
2. To produce estimates of the potential effect size (mean and standard deviation [SD]) of the web-based intervention on purchases of ready meals and pizzas (primary outcome).
3. To produce estimates of the potential effect size (mean and SD) of the intervention on purchases of all foods; purchases of fruit and vegetables; and psychosocial variables associated with label use (secondary outcomes).
4. To conduct a process evaluation consisting of semi-structured interviews and web analytics to explore the acceptability of the trial to both participants and the participating supermarket chain, to explore unintended consequences of the intervention, and explore the take up of different elements of the intervention.

Outcome measures

<u>Recruitment, retention and data completeness</u>

Participants will be deemed to have been fully retained in the study if a) they do not contact the study team to withdraw or unsubscribe, and b) if psychosocial questionnaires sent at T1 and T2 are completed. Partial retention rates for those who only complete the questionnaire at T1 or who only contribute food purchase data will also be calculated. Recruitment and retention rates from different socioeconomic groups (measured by area-level deprivation) will be assessed by comparison of the socioeconomic profile of the recruited sample with the profile of the whole loyalty card database from which the sample was drawn.

See dummy table 1 and figure 1 for presentation of results.

Effect sizes

The research team will receive electronic sales data for all food purchases during the study period from the participating supermarket at two stages: after allocation and after completion of the study. The primary outcome measures for the main trial will be healthiness of ready meals and pizzas that carry traffic light labelling. For each participant, mean healthiness of all ready meals and pizzas purchased during the entire time period will be assessed in –T1, T1 and T2 and differences between intervention and control arms at T1 and T2 will be controlled for differences at baseline (-T1). Purchase data will be collected via electronic sales data linked to participants' loyalty cards. Comparisons between intervention and control at T1 will measure the immediate effect of the intervention, and at T2 will measure whether the effect is sustained for the following 12 weeks after the intervention is removed. The 'healthiness' of each purchased ready meal or pizza will be a combination of the information provided on the traffic light label, weighted by factors derived from a parallel choice experiment assessing the importance of different elements of the label (manuscript under preparation).

See dummy table 2 and 3 for presentation of results.

Secondary outcome measures (assessed as difference in means and SD between intervention and control) will be:

1. Number of ready meals and pizzas purchased in T2 / T1.
2. Amount (£) of ready meals and pizzas purchased in T2 / T1.
3. Total amount (g) of fat, saturated fat, sugar and salt in ready meals purchased in T2 / T1.
4. Amount (£) of all foods purchased in T2 / T1.
5. Amount (£) of fruit and vegetables purchased in T2 / T1.
6. Psychosocial variables including Beliefs, Attitudes, Intention, Outcome expectancies and procedural knowledge measured in T2 / T1.

See dummy tables 4 and 5 for presentation of results.

Statistical analysis

Demographic characteristics and outcomes data will be summarised with counts and percentages for categorical variables, means (standard deviations) for normally distributed continuous variables and medians (with interquartile or simple ranges) for other continuous variables. At time points T1 and T2, repeated measures ANCOVA will be used to assess differences between intervention and

control arms, adjusted for gender, dependent children and baseline measures. If outcome data are not normally distributed then differences will be assessed either using transformed data or by using appropriate non-parametric tests. Results will be presented as point estimates accompanied by 95% confidence intervals. Analyses will be conducted on an 'intention to treat' basis (i.e. data for participants who unsubscribe from the study will be used in the final analyses). Subgroup analyses by socioeconomic status will be conducted to assess potential impact of the intervention on social inequalities. Since this is a pilot study with a sample size based on a small effect size and unclear recruitment rates, it is not guaranteed that the study will be adequately powered to detect differences between intervention and control arms, particularly in sub-analyses. The socioeconomic status of the participants will be compared with that of the loyalty card database from which they are drawn to assess inequalities in recruitment, using area-level deprivation measures.

Missing outcome data (MOD) can be generated in a number of ways. For both the electronic sales data and questionnaire data, MOD can be generated by participants withdrawing post-randomisation. For the questionnaire data, MOD can be generated by failure to complete some or all of the questions within a questionnaire. Importantly, the primary outcome variable (average healthiness of ready meals and pizzas purchased in T-1, T1 and T2) can produce MOD if the participant did not purchase any ready meals or pizzas using their Cooperative member card in any of the three study phases. A systematic review of methods used to cope with MOD in intention-to-treat analyses demonstrated that there is no consensus towards a preferred approach, with arguments for restricting to complete case analysis and for imputation of missing data[1]. For the FLICC study we will deal with MOD by employing single imputation techniques for all missing data. The imputation method will use regression analysis with gender and dependent children as predictor variables (NB: these variables were used for block randomisation, so are guaranteed to be equally represented in control and intervention groups). The imputation dataset will be all observations within T-1 for MOD at T-1, and equivalent for phases T1 and T2.

Note on missing questionnaire data: We proposed that we would impute data for missing data in the baseline questionnaire, but not impute for questionnaires 2 and 3. This is because of the expectation that there will be low return rates for Q2 and Q3, and hence imputing data for these questionnaires would result in a severe bias towards the null hypothesis.

So, if (for example) we receive 150 Q2 questionnaires, then the analysis of these data will have an n of 150, and if any of the 150 did not complete the baseline questionnaire then missing data will be imputed (using the same method as will be applied to the electronic sales data). This is somewhat of a move away from the 'intention-to-treat' design (although that interpretation is not universal) but beneficial in this scenario where data are likely to be sparse.

[1] Alshurafa M, Briel M, Akl E, et al. Inconsistent definitions for intention-to-treat in relation to missing outcome data: systematic review of the methods literature. *PLoS One,* 2012;7(11):e49163.

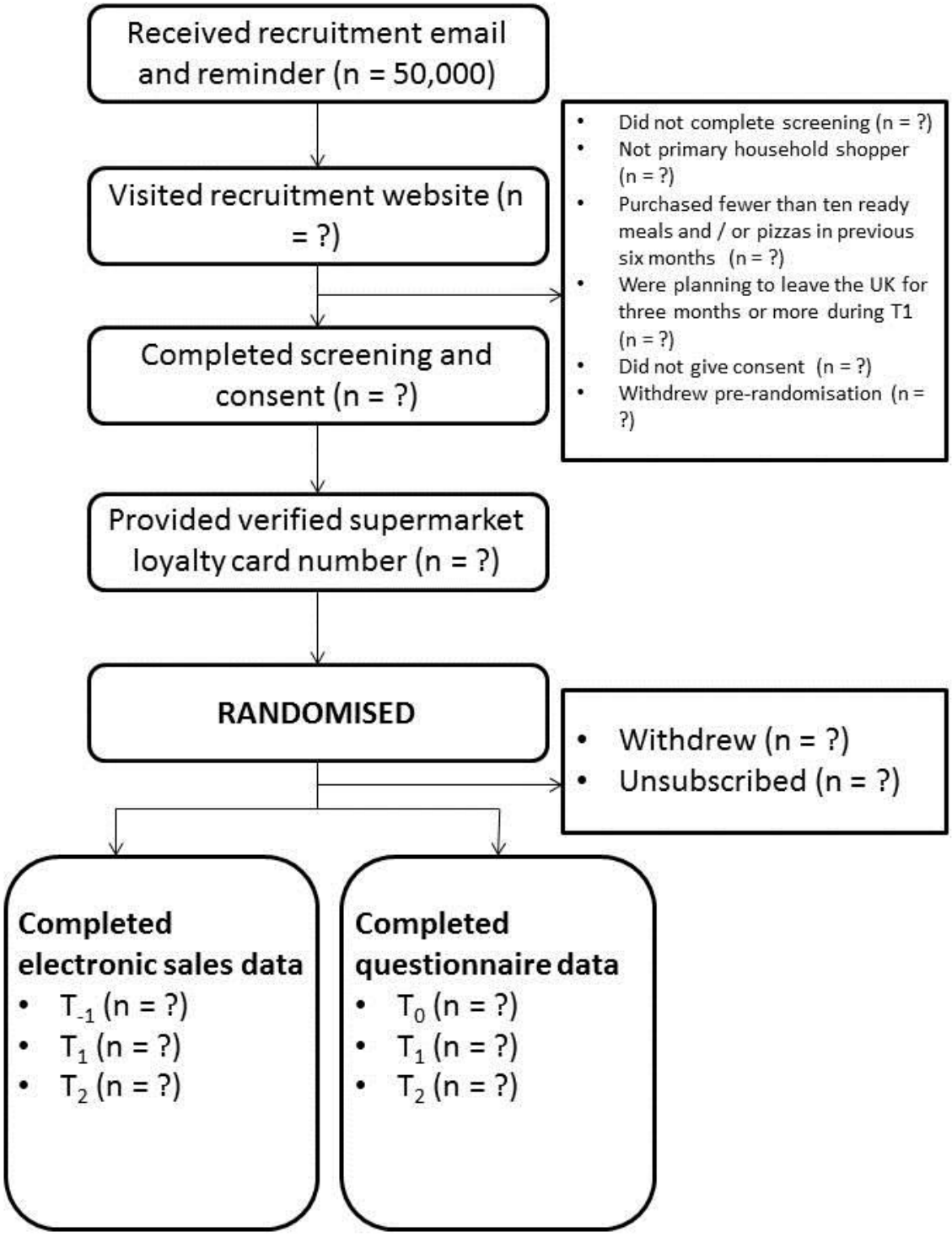
With regard to electronic sales data, all missing data at all time points will be imputed. As we are likely to have far less missing data in the electronic sales data this is likely to result in a much more moderate bias towards the null hypothesis, and it aligns with our ‘intention-to-treat’ design.

Dummy table 1: Recruitment, retention and data completeness by deprivation quintile

	Recruitment email list	Randomised sample	Retained participants	Participants with complete data
Total				
Q1				
Q2				
Q3				
P (difference to randomised sample)				
Male				
Female				
P (difference to randomised sample)				
No dependent children				
Dependent children				
P (difference to randomised sample)				
Social class				
Etc.				

Notes: 'Retained participants' refers to all participants that did not withdraw or unsubscribe; 'participants with complete data' refers to all participants that provided electronic sales data and questionnaire data at all time points.

Dummy figure 1: study flow diagram



Dummy table 2: Primary outcome measure results – healthiness of ready meals and pizzas purchased by intervention and control arms in three study phases

	T-1	T1	T2
Intervention	Mean (SE)	Mean (SE)	Mean (SE)
Control	Mean (SE)	Mean (SE)	Mean (SE)
p*			
Missing data**			

* Results of ANCOVA comparing intervention and control adjusted for gender, dependent children and healthiness of ready meals and pizzas purchased at T-1.

** Missing data could be from study withdrawal or zero purchase of ready meals and pizzas whilst using supermarket loyalty card during study periods. Single imputation used to replace missing data in analyses

Dummy table 3: Primary outcome measure results – healthiness of ready meals and pizzas purchased by intervention and control arms in three study phases, sub-analyses by socioeconomic group

Low SES	T-1 (n = ?)	T1 (n = ?)	T2 (n = ?)
Intervention	Mean (SE)	Mean (SE)	Mean (SE)
Control	Mean (SE)	Mean (SE)	Mean (SE)
p*			
Missing data**			
High SES	T-1 (n = ?)	T1 (n = ?)	T2 (n = ?)
Intervention	Mean (SE)	Mean (SE)	Mean (SE)
Control	Mean (SE)	Mean (SE)	Mean (SE)
p*			
Missing data**			

* Results of ANCOVA comparing intervention and control adjusted for gender, dependent children and healthiness of ready meals and pizzas purchased at T-1.

** Missing data could be from study withdrawal or zero purchase of ready meals and pizzas whilst using supermarket loyalty card during study periods. Single imputation used to replace missing data in analyses

Dummy table 4: Secondary outcome measure results – difference between intervention and control arm (standard error)

	T-1	T1	T2
Number of ready meals / pizzas purchased			
Amount (£) of ready meals / pizzas purchased			
Total fat (g) purchased per week			
Saturated fat (g) purchased per week			
Total sugar (g) purchased per week			
Salt (g) purchased per week			
Amount (£) of fruit and vegetables purchased			
Amount (£) of all food purchased			
Missing data***			

* p<0.05; ** p<0.01 from ANCOVA comparing intervention and control adjusted for gender, dependent children and results at T-1.

*** Missing data from withdrawal only. Single imputation used to replace missing data in analyses