STATISTICAL ANALYSIS PLAN

The OLS Study

The effectiveness of individual-level and environmental-level interventions on food choices:

an experimental online supermarket study

Version number and date: 1.0, 13-Jul-2018

Version History

Version:	Version Date:	Changes:

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1 INTRODUCTION

1.1 PREFACE

The Trial Statistician (Dr Jose Ordoñez-Mena), Chief Investigator (Dr Carmen Piernas-Sanchez), and Trial Manager/Co-Investigator (Dr Dimitrios Koutoukidis) have contributed to and approved the statistical analysis plan (SAP). The SAP supports the study protocol version 2.0 and dated 05-Feb-2018. Analysis will be carried out using up-to-date versions of Microsoft Word and R.

1.2 PURPOSE AND SCOPE OF THE PLAN

The purpose of the plan is to complete the main analysis as stated in the protocol.

1.3 TRIAL OVERVIEW

High saturated fat intake increases the risk of cardiovascular disease. Dietary counselling has proven to have only modest effects. An approach that also includes environmental restructuring may reduce the risk of widening inequalities and may be more successful in sustaining individual behaviour change. Food purchasing is a key antecedent of food consumption, therefore individual-level interventions targeting the nutritional quality of the grocery shopping present a clear opportunity for action. Online supermarkets offer unique opportunities to deliver and support complex nutrition interventions to shape food purchasing patterns at scale, but research in this arena is still in its infancy and more solid evidence is required to develop a truly effective intervention with population-level impact.

The aim of this project is to test the effects of an individual-level intervention and an environmental-level intervention, separately and in combination, on SFA in a sample of UK adults.

1.4 OBJECTIVES

<u>Primary objective</u>

To investigate the magnitude of saturated fat achieved in the shopping basket in response to an individual-level intervention and an environmental-level intervention, separately and in combination, compared to control (no intervention).

<u>Secondary objectives</u>

To investigate the effect of the interventions on:

i. the proportion of products with less than 1.5% saturated fat in the final basket
ii. the overall cost of the final shopping basket
iii. the diet composition of the shopping basket

To investigate the effect of the individual-level intervention on

iv. saturated fat change per swap accepted
v. the proportion of swaps accepted out of those offered overall
vi. the proportion of swaps accepted out of those offered by magnitude of reduction
vii. the proportion of swaps accepted out of those offered by type of food group
viii. the proportion of accepted swaps out of total shopping basket items

2 TRIAL DESIGN

This is a 2x2 factorial randomised controlled trial of an individual-level and an environmental-level intervention to reduce the SFA content of the total shopping basket during an online shopping experiment. Each participant will be randomly allocated on an 1:1:1:1 basis to one of the four trial arms and participate in the study for about 30 minutes in total (see Appendix A of the study protocol for a study flow chart). The interventions are detailed on section 7 of the study protocol. UK adults with no dietary restrictions who are the main grocery shoppers for their household will be invited to participate through an online research agency (https://www.prolific.ac/).

Following consent, participants will complete a baseline questionnaire on demographic, shopping, and health data. Participants will complete a short post-intervention survey about the acceptability of the two interventions in the online shopping task and their usual shopping behaviours.

The investigators and the participants will not be blinded. The outcome assessor and the trial statistician will be blinded.

2.1 OUTCOMES MEASURES

2.1.1 PRIMARY OUTCOME

As primary outcome, we will compare the difference in the saturated fat content of the final basket (measured in % of total energy) between each of the four trial arms.

2.1.2 SECONDARY OUTCOMES

The following outcomes will be compared between each of the four trial arms:

i. difference in the proportion of products with lower saturated fat in the final basket (%)
ii. difference in the overall cost of the final shopping basket (£) weighted for the size of the basket (g)
iii. difference in the total energy, energy density, sugars (% energy), and salt (g/100g) content of the shopping basket

The following outcomes will be compared between the single individual-level intervention (swaps only) and the combined intervention arms

iv. difference in % saturated fat content per swap accepted (% energy intake)
v. difference in the proportion of swaps accepted out of those offered (%)
vi. difference in the proportion of swaps accepted out of those offered (%) by median observed change in saturated fat
vii. difference in the proportion of swaps accepted out of those offered (%) for (a) butter, margarine, and spreads, (b) cheese, (c) milk, (d) meat, and (e) sweets and desserts
viii. difference in the proportion of accepted swaps out of total shopping basket items (%)

Non-efficacy outcome:

Rating scores from the survey on acceptability and open-ended answers from the follow-up questionnaires

2.2 TARGET POPULATION

Inclusion Criteria

- UK adults, aged ≥18 years.
- Able to speak and read English.
- Willing and able to give informed consent for participation in the study.
- Being the main (or shared) grocery shopper for their household.
- Having access to a computer and Internet.

Exclusion Criteria

- Having any dietary restriction.

2.3 SAMPLE SIZE

There are no previously reported standard deviations of the mean difference from similar trials to guide the estimation of the standard deviation in our trials, and, thus, for the calculation of the sample size.

Therefore, we conducted an initial pilot to estimate the standard deviation and adapt the power calculation if necessary. The initial plan was to recruit 500 people for the pilot and include those in the analysis of the full trial. Due to logistical constraints, 129 people were recruited for an independent pilot. This sample included 31-33 participants per arm with valid data, as our pre-defined completion criterion (i.e. people who bought at least 5 items from the list), and showed a standard deviation of 6.5%.

If we were to observe a minimally clinically relevant 2% reduction in SFA (assuming a 7% - rounded 6.5 - standard deviation) in the total basket between any of the 4 groups using intention to treat analyses with 90% power and two-sided α=0.05, we would require 258 per group giving a total of 1032 participants. A final sample of 1240 participants would account for 20% non-completion through participants not completing the shopping task.

2.4 RANDOMISATION AND BLINDING IN THE ANALYSIS STAGE

The statistician generated the randomisation sequence in R (see Appendix 1 for R code) and the investigator uploaded the sequence to the survey platform (https://redcap.phc.ox.ac.uk/). Randomisation was performed by the survey platform via computerised random number generation on an 1:1:1:1 basis with random block sizes and participants were directed to a website that introduces an online shopping task. Allocation concealment was achieved, as participants were recruited from independent research panels and were directed for automatic randomisation in the survey platform.

Investigators were not blinded to intervention allocation but they were not able to manipulate any study parameter following the initial study set up, as all study procedures are taking part in the online platform. The outcome assessment is blinded, as it happens automatically in the online platform. The statistician who will analyse the data will be blinded to intervention allocation. Due to the nature of the intervention, it will not be possible to blind participants to the intervention. However, participants will only be aware of the trial arm that they are exposed to and will be unaware of the other trial arms.

3 ANALYSIS – GENERAL CONSIDERATIONS

3.1 DESCRIPTIVE STATISTICS

A table will present the baseline characteristics by trial arm and overall (Appendix 2). The table will include age, gender, ethnic group, weight, BMI, education, household income, household size, household supermarket spending, online shopping, and health conditions. Continuous variables will be summarised using means and standard deviations. Medians with interquartile ranges will be presented where appropriate. Categorical variables will be summarised using counts and percentages. Data will be analysed using R.

3.2 CHARACTERISTICS OF PARTICIPANTS

Baseline characteristics will include age, gender, ethnic group (White, Black, Asian, Mixed, Other), BMI (continuous and categories based on the WHO cut-offs), education (none, secondary education, higher education), household income (<£15.5k, 15.5-25k, 26-39, ≥40), household size (continuous in number of people), household supermarket spending (continuous in £), online shopping for groceries (Once per week or more often, 1-3 times per month, 4-11 times in the last year, 1-3 times in the last year, Never or not in the last year), online shopping for non-food items (Once per week or more often, 1-3 times per month, 4-11 times in the last year, 1-3 times in the last year, Never or not in the last year) and history of health conditions (heart disease, high cholesterol, high blood pressure, diabetes, obesity or overweight, COPD, none of the above).

3.3 DEFINITION OF POPULATION FOR ANALYSIS

We will use an intention-to-treat approach (based on the trial arm participants were initially randomised) to analyse all participants who completed the shopping task (available case analysis). Completion of the shopping task will be defined as purchase of at least 5 out of 10 items from the categories listed in section 7 of the study protocol. The sample size calculation has accounted for a 20% non-response rate. We do not expect major protocol violations, such as violation of entry criteria, due to the online computerised nature of the trial management and delivery.

3.4 DATA MONITORING COMMITTEE AND INTERIM ANALYSES

Due to the low risk of harm and short length of the intervention, a data monitoring committee will not be needed and an interim analysis will not be conducted.

4 PRIMARY ANALYSIS

4.1 PRIMARY OUTCOME

The null hypothesis is that this is no effect of the interventions and the two-sided alternative hypothesis is that there is a difference in saturated fat measured in % of total energy between any of the 4 trial arms. The observed difference will be interpreted in light of a 2% reduction in saturated fat intake which is deemed

minimally clinically relevant. The sum of saturated fat (g) will be multiplied by 9 and then divided by the sum of the energy (kcal) in each participant's final basket.

Two-way analysis of variance (ANOVA) will be used to test for the difference between

- SFA in each intervention group compared to control
- SFA in the combined intervention group compared to single intervention groups
- SFA in one single intervention group versus the other single intervention group
- SFA in the combined intervention group compared to control.

Estimates of intervention effects will be reported with confidence intervals.

4.2 HANDLING MISSING DATA

The percentage and absolute withdrawal in each study arm will be reported in the CONSORT flow-chart and reasons for withdrawal will be documented. As the outcome variables (saturated fat in g and energy in kcal) are automatically calculated based on the food database embedded in the online platform, we do not anticipate any missing for the population for analysis.

4.3 HANDLING OUTLIERS

For the analysis of the primary outcome, we do not expect significant outliers based on our definition of population for analysis (section 3.3). Data outliers will be defined as being at least three standard deviations from the mean of its distribution in the variable at that time-point and will be cross-checked. Given calculation of the primary outcome using the pre-existing nutrition database, we do not expect significant outliers in the primary outcome measure. Outliers will be included in the analysis and a sensitivity analysis will be conducted by setting outliers to be missing.

4.4 MULTIPLE COMPARISONS AND MULTIPLICITY

As the comparisons have been pre-specified, we will not correct for multiple testing.

4.5 MODEL ASSUMPTIONS

The appropriateness of the normality, no outliers, and homogeneity of variances assumptions required for the ANOVA model will be assessed using residual and other diagnostic plots, the Shapiro-Wilk test of normality, and the Levene's test for equality of variances. Where concern is indicated, a transformation and/or a nonparametric method will be used to address gross deviations from the assumptions. It is unlikely that the primary outcome will need to be transformed in order to make use of methods assuming normality.

5 SECONDARY ANALYSIS

5.1 SECONDARY OUTCOMES

Two-way ANOVA will be used to test for the difference between each trial arm

- in the proportion of products with lower saturated fat in the final basket (%)
- difference in the overall cost of the final shopping basket (£) weighted for the size of the basket in grams
- difference in the total energy, energy density (kcal/g), sugars (% energy) and salt (g/100g) content of the shopping basket

Independent t-test will be used for the difference between the single individual-level intervention (swaps only) and the combined intervention arms

- difference in % saturated fat content per swap accepted (% energy intake)
- difference in % swaps accepted out of those offered (%)
- difference in % swaps accepted out of those offered (%) by median observed change in saturated fat
- difference in % swaps accepted out of those offered (%) for (a) butter, margarine, and spreads, (b) cheese, (c) milk, (d) meat, and (e) sweets and desserts
- difference in % swaps accepted out of the total number of products in the basket

5.2 NON-EFFICACY OUTCOMES

The rating scores of the acceptability of swaps will be presented descriptively.

The open-ended follow-up questionnaire will be analysed using content analysis in MS Excel.

6 SUBGROUP ANALYSES

We do not expect the intervention effect to differ between subgroups. However, we will conduct exploratory analysis by gender, age group stratified by median, ethnic group (White vs Non-White), BMI stratified into <30 and ≥30kg/m^2 groups, highest education level (lower vs. higher), and household income (lower vs. higher) provided we have sufficient numbers within each subgroup (n≥30). We will also run an analysis by the purchased food group.

7 ADDITIONAL EXPLORATORY ANALYSIS

We have not planned any additional exploratory analysis.

8 SAFETY ANALYSIS

Due to the low risk of harm, there is no plan for a safety analysis.

8.1 ADVERSE EVENTS

This is a simple online task and we cannot foresee any unintended or adverse effects due to participation.

9 VALIDATION

A senior statistician will double check the analysis plan and code, and re-run the code for the primary analysis.

10 CHANGES TO THE PROTOCOL OR PREVIOUS VERSIONS OF SAP

N/A

11 APPENDICES

Appendix I. Randomisation code in R

```
install.packages("blockrand")
library(blockrand)

set.seed(123)

rand <- blockrand(n=1240, levels = c("26","27","28","29"))

table(rand$treatment)

table(rand[1:1240,"treatment"])

save.folder <- '/Users/dimitrioskoutoukidis/Desktop/'

write.csv(rand[,c("id","treatment")], row.names = FALSE,
          paste0(save.folder, 'OLS Random Allocation.csv'))
```

Appendix 2: Template tables for presentation of results

Baseline characteristics of participants

N(%), unless otherwise specified	Control (n=)	Swaps (n=)	Positioning (n=)	Combination (n=)
Age, years, mean (SD)				
Gender, female				
BMI, kg/m^2, mean (SD)				
BMI categories				
Underweight (<18.5)				
Normal weight (18.5-24.9)				
Overweight (25-29.9)				
Obesity (≥30)				
Ethnic group				
White				
Black / Asian				
Mixed / Other				
Education				
No formal qualifications				
Secondary education				
Higher education				
Household income				
Lower (≤£25k)				
Middle (£26-39k)				
Higher (≥£40k)				
Household size, median (IQR)				
Household supermarket spending, median (IQR)				
Online grocery shopping				
≥1 per week				
1-3 times per month				
4-11 times in the last year				
1-3 times in the last year				
Never or not in the last year				
Online non-grocery shopping				
≥1 per week				
1-3 times per month				
4-11 times in the last year				

1-3 times in the last year				
Never or not in the last year				
Health history				
Heart disease				
High cholesterol				
High blood pressure				
Diabetes				
Overweight/obesity				
COPD				

Primary and secondary outcomes between trial arms, all mean± SD

	Mean± SD				Between group difference (95% CI)					
	Control (n=)	Swaps (n=)	Positioning (n=)	Combination (n=)	Swaps vs Control	Positioning vs Control	Combination vs Control	Combination vs Swaps	Combination vs Positioning	Positioning vs Swaps
Primary outcome										
SFA (% kcal)										
Secondary outcomes										
% of products with <1.5% SFA										
Cost (£/100g)										
Total energy (kcal)										
Energy density (kcal/g)										
Sugar (% kcal)										
Salt (g/100g)										

Outcomes between swaps and combination arms

	Swaps		Combination		Combination vs Swaps
	Mean± SD	n	Mean± SD	n	Between group difference (95% CI)
SFA (% kcal) per accepted swap					
% swaps accepted out of swaps offered					
total					
High SFA change					
Low SFA change					
Butter, margarine, spreads					
Cheese					
Milk					
Meat					
Sweets and desserts					
% of accepted swaps out of total number of basket items					

Subgroup analysis

	Mean± SD, N								Between group difference (95% CI)					
SFA (% kcal)	Control		Swaps		Positioning		Combination		Swaps vs Control	Positioning vs Control	Combination vs Control	Combination vs Swaps	Combination vs Positioning	Positioning vs Swaps
Sex														
Female														
Male														
Age														
Median and above														
Below median														
Ethnic group														
White														
Non-White														
BMI														
<30														
>30														
Education														
Lower														
Higher														
Household income														
Lower														
Higher														

Main effects and interactions

	Mean± SD				Between group difference (95% CI)		Interaction coefficient (95% CI)
	Swaps (n=)	No Swaps (n=)	Positioning (n=)	No Positioning (n=)	Swaps vs Control	Positioning vs Control	
Primary outcome							
SFA (% kcal)							
Secondary outcomes							
% of products with <1.5% SFA							
Cost (£/100g)							
Total energy (kcal)							
Energy density (kcal/g)							
Sugar (% kcal)							
Salt (g/100g)							

Post-task survey on 3 most important factors affecting food purchasing decisions (Yes/No)

N(%)	Control (n=)	Swaps (n=)	Positioning (n=)	Combination (n=)	Total (n=)
Price					
Appearance					
Taste					
Habits					
Healthiness					
Convenience					
Special offers					
Organic					
Special diet (e.g. gluten free)					
Other (e.g. animal welfare, locally produced, packaging))					

Post-task survey on looking at nutrition labelling while at usual grocery shopping (total n=)

N(%)	Always	Often	Sometimes	Rarely	Never
Calories					
Fat					
Saturated fat					
Sugar					
Salt					