NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

SHOP
Preventing cardiovascular disease in primary care

STATISTICAL ANALYSIS PLAN

Study Title:
Primary Care Shopping Intervention for Cardiovascular Disease Prevention (PCSHOP)

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Table of Contents

INTRODUCTION

PREFACE

The Trial Statistician (Dr Jason Oke), Investigators (Dr Carmen Piernas-Sanchez, Prof Susan Jebb, Prof Paul Aveyard), and Trial Manager (Dr Claire Madigan/Dr Joy Rahman) have contributed to and approved the statistical analysis plan (SAP). The SAP supports the study protocol version 4.0 and dated 11/12/2018. Analysis will be carried out using up-to-date versions of Stata and/or R.

PURPOSE AND SCOPE OF THE PLAN

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

TRIAL OVERVIEW

A diet high in saturated fat (SFA) increases the risk of cardiovascular disease (CVD) and intakes in the UK exceed dietary recommendations. The Primary Care Shopping Intervention for Cardiovascular Disease Prevention (PCSHOP) study aims to test the effect of an intervention for people with raised low density lipoprotein (LDL) cholesterol involving health professional (HP) advice alone, or in combination with personalised feedback based on nutritional analysis of grocery store loyalty card data, on SFA intake and blood lipids in comparison with no intervention.

The hypothesis is that an intervention involving health professional advice alone can motivate people to reduce their SFA intake (primary outcome) and lower LDL cholesterol (secondary outcome) compared with no intervention, and that providing additional, personalised feedback based on the nutritional content of grocery purchases will be more effective than brief advice only or no intervention.

Other secondary outcomes include changes in other blood lipids and the SFA content of food purchases, with process measures to consider the feasibility and acceptability of this novel intervention.

OBJECTIVES

<u>Primary objective</u>

To develop and test the effectiveness of a behavioural intervention to reduce saturated fat (SFA) intake through brief advice from a qualified health professional alone (intervention 1 – “Brief Support”) or in combination with feedback on food purchasing behaviours (intervention 2 – “Brief Support plus Shopping Feedback”), compared to control (“No intervention”).

Secondary objectives

To test the effects of the intervention on:

- Other measures of dietary intake, including changes in mean total energy intake, total fat, total sugars, fibre and salt; and intake of high SFA food groups between baseline and 3 months.
- Measures of food purchases including changes in mean %SFA from total purchases; energy density, total fat, sugar, fibre and salt from purchases; proportion of food items with low SFA (e.g. products with ≤1.5 grams of SFA per 100 grams of the product); mean total cost of the shopping basket (£) between baseline and 3 months.
- Biochemical markers of CVD risk, including changes in mean LDL-cholesterol, HDL-cholesterol, total cholesterol and triglycerides; systolic and diastolic blood pressure between baseline and 3 months.
- Body weight, including changes (absolute (kg) and relative (%)) in body weight between baseline and 3 months.
- Feasibility of the intervention, including willingness of participants to take part in the study and be randomised to measure recruitment rates; follow-up rates to measure programme attendance and retention; and process measures such as the acceptability of the intervention for participants and health professionals and the uptake of the intervention; and the fidelity of the intervention delivery.
- Qualitative study outcomes: Themes and sub-themes pertaining to the participants' (i) knowledge, (ii) perceived barriers, facilitators and actions, (iii) contextual influences, and (iii) value of the healthcare advice provided.

TRIAL DESIGN

This is an individually randomised, 3 arm, parallel controlled open-label trial. Each participant will be randomly allocated on a 3:3:1 basis to one of the 2 active interventions ("Brief Support" or "Brief Support plus Shopping Feedback") or control ("No intervention").

Patients' participation in the study will last 3 months from randomisation to final follow-up. The interventions are detailed on section 9 of the study protocol. The study population will include 112 adults ≥18 years of age with confirmed high LDL cholesterol (>3 mmol/L) at baseline, who will be recruited and randomised to intervention or comparator groups.

At the baseline visit participants will provide full informed consent and a blood sample by fingerprick will be taken by the central research team. Additionally, the central research team will collect other baseline measures, including two 24h dietary recalls, weight and height and blood pressure. All participants will come back after 3 months for follow up in which some outcome measures collected at baseline will be repeated, including the blood sample, the 24h dietary recalls, weight, blood pressure, and a questionnaire to assess acceptability of the intervention.

Due to the nature of the intervention, it will not be possible to blind participants, clinicians or some of the study team to the treatment allocation once the intervention commences, but they will be blind at the point of randomisation. Nevertheless, the primary outcome will be a measure of

saturated fat intake collected through a web-based questionnaire which individuals will fill in individually without any involvement from the study team. The brief advice intervention will be delivered by the practice nurse, who won't be aware of the treatment allocation within the active intervention arms. The trial statistician will be blinded to the data analysis.

OUTCOMES MEASURES

PRIMARY OUTCOME

Primary Objective	Measures	Timepoints
To test a behavioural intervention to promote reductions in saturated fat (SFA) intake through brief advice from a qualified health professional alone or in combination with feedback on food purchasing behaviours	Change in SFA intake (% EI) from baseline to follow up, measured using 2 x 24h dietary recalls using the Web-Q instrument.	Mean % SFA intake at baseline and 3 months.

The primary analysis will test for:
- A difference in the change (from baseline to follow up) in % SFA intake between each intervention group compared to control;

- A difference in the change (from baseline to follow up) in % SFA intake between the two active intervention arms.

SECONDARY OUTCOMES

Objectives	Outcome Measures	Timepoints of evaluation of this outcome measure
Secondary Outcomes		
1. Food intake	1. Changes in SFA intake (g, kcal) and frequency of consumption of high/low SFA food groups using 2 x 24h dietary recalls.	1. Mean intake (g, kcal) of SFA and frequency of low/high SFA foods at baseline and 3 months
2. Food purchases	2. Changes in SFA from total purchases; purchases of food items with high/low SFA;	2. Mean %SFA and SFA per £ from total purchases; mean volume of food items with low/high SFA at baseline and 3 months.
3. Biochemical markers of CVD risk	3. Changes in LDL-cholesterol, HDL-cholesterol, total cholesterol, non-HDL cholesterol, total cholesterol/HDL ratio and triglycerides;	3. Mean LDL-cholesterol, HDL-cholesterol, total cholesterol, non-HDL cholesterol, total cholesterol/HDL ratio and triglycerides at baseline and 3 months.

Non-efficacy Outcomes		
1. Intake of other nutrients	1. Changes in energy intake, total fat, total sugars, fibre and salt using 2 x 24h dietary recalls.	1. Mean total energy intake, total fat, total sugars, fibre and salt at baseline and 3 months.
2. Other purchasing patterns	2. Changes in energy density, total fat, sugar, fibre and salt from purchases; mean total cost of the shopping basket (£).	2. Mean energy density, total fat, sugar, fibre and salt from purchases; and mean total cost of the shopping basket (£) at baseline and 3 months.
3. Blood pressure	3. Changes in systolic and diastolic blood pressure.	3. Mean systolic and diastolic blood pressure at baseline and 3 months.
4. Body weight	4. Changes (absolute (kg) and relative (%)) in body weight.	4. Mean body weight at baseline and 3 months.
Feasibility and Process Measures		
Recruitment rates	Willingness of participants to take part in the study and be randomised.	Number of participants who accept the invitation, consent to take part in the study and are randomised at baseline
Follow-up rates	Programme attendance and retention.	Number of participants who return for the follow up visit at 3 months
Acceptability and views of the intervention; and other process measures	Acceptability of the intervention for participants and health professionals; uptake of knowledge, motivation and swaps accepted.	Questionnaires at baseline, 3 months and immediately after the intervention is delivered. Number and types of swaps purchased during the intervention.
Fidelity of the intervention	To evaluate whether the intervention has been delivered as intended	Content/timing of the intervention session, number of shopping reports sent
Qualitative Sub-study	To conduct a semi-structured, one-to-one, telephone interview with a sub-sample of the PC-SHOP study participants to explore issues related to food purchasing behaviours, including knowledge, perceived barriers, facilitators and actions, contextual influences, and value of the healthcare advice provided.	Themes and sub-themes pertaining to the participants' (i) knowledge, (ii) perceived barriers, facilitators and actions, (iii) contextual influences, and (iii) value of the healthcare advice provided.

TARGET POPULATION

Inclusion Criteria

- Male or Female, aged 18 years or above.
- Express a desire for support to improve the nutritional quality of their diet to reduce their CVD risk.
- Primarily responsible for household shopping (e.g. complete at least half of their household shopping).
- Shops mainly at Tesco (e.g. at least once/week instore and/or online) using a Tesco's storecard.
- Have had a Tesco's storecard registered exclusively under their name for at least 3 months before recruitment.
- Computer literate (e.g. use email regularly and is able to perform dietary questionnaires online).
- Participant is willing and able to give informed consent for participation in the study.
- With confirmed LDL cholesterol above 3 mmol/L at recruitment.

Exclusion Criteria

- Unable to read and understand the instructions provided in English.
- Pregnant, or planning to become pregnant during the course of the study.
- Started cholesterol-lowering medication in the last 3 months.
- Planned changes to cholesterol-lowering medication in the next 3 months.
- Existing cardiovascular conditions: heart attack or stroke or new diagnosis of atrial fibrillation within the last 3 months; heart failure of grade II New York Heart Association and more severe, or prolonged QT syndrome, angina, Arrhythmia, or familial hyperlipidaemia.
- Currently or recently (within the last 3 months) participating in another intervention study which likely affects the outcomes measured in this study.
- Patients that the GP judges not able to meet the demands of the study or unlikely to adhere to study procedures as stated in the protocol.

SAMPLE SIZE

The total number of participants we intend to recruit for this study is 112, with a sampling ratio of 1:3:3. Therefore, 16 participants will be allocated to control, and 48 participants will be allocated to each of the two active interventions.

Previous studies such as highly controlled interventions in populations with high CVD risk have achieved absolute changes in %SFA intakes of around 4-5%[6 7], and a short-term change in LDL-cholesterol of 0.32 mmol/L by a low-intensity primary care-based intervention[10]. Attrition rates have been reported to be quite low in short term primary care-based trials[10 20], so we could assume around 10% attrition rate in our study. In order to detect a reduction of 3% in %SFA intake (3% standard deviation) between each intervention and control with 90% power and two-sided α=0.05 using intention-to-treat analyses, we will need 16 participants in the control group and 48 in each intervention arm to account for 10% attrition and multiple comparisons. By recruiting 48

participants in each active intervention arms, we will be able to detect a further difference between these two arms of 2% (3% SD) with 90% power.

In addition, this sample size will allow to detect a change in LDL cholesterol of 0.3 mmol/L (SD 0.8) between each intervention and control with 60% power using a 2-sided α=0.05.

Randomisation and blinding in the analysis stage

An independent statistician (Dr. Mei Man Lee) generated the randomisation sequence and the data manager uploaded the sequence to the database (https://redcap.phc.ox.ac.uk/). Randomisation was performed by the platform via computerised random number generation on a 3:3:1 basis with random block sizes of 7. RedCap program ensures full allocation concealment as information on future allocations are not accessible to the person randomising.

Investigators were not blinded to intervention allocation but the primary outcome is a measure of saturated fat intake collected through a web-based questionnaire which individuals will fill in individually without any involvement from the study team. Furthermore, the statistician who will analyse this data will be blinded to intervention allocation.

Analysis – General considerations

Data cleaning

Prior to the final data lock, data cleaning will be performed, including checking outcome variables were in the correct ranges.

Descriptive statistics and participant characteristics

A table will present the baseline characteristics by trial arm and overall (Appendix 1). The table will include age, gender, ethnic group, BMI, blood pressure, education, household size, alcohol, smoking, grocery shopping habits and relevant health conditions and medications. 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 and/or Stata.

Baseline characteristics will be coded as: age (years); gender (men, women); ethnic group (White, Black, Asian, Mixed, Other); BMI (kg/m^2 and categories based on the WHO cut-offs; blood pressure (mmHg, lowest reading of the 3 collected); education (none, secondary education, higher education); household size (continuous in number of adults plus children); grocery shopping habits (e.g. spending >£25 on groceries > once a week, once a week, once a fortnight, once a month, < once a month); and relevant health conditions (CVD, high blood pressure, diabetes, AF, CKD) and medications (e.g. statins).

Definition of population for analysis

The primary statistical analysis of efficacy outcomes will be carried out on the basis of intention-to-treat (ITT) (based on the trial arm to which participants were initially randomised) to analyse all participants who complete the study (complete case analysis). We will endeavour to obtain full

follow-up data on every participant to allow full ITT analysis, but we will inevitably experience the problem of missing data due to withdrawal, loss to follow up, or non-response to questionnaire items. The sample size calculation has accounted for a 10% non-response rate.

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.

Primary analysis

Primary outcome

The primary outcome analysis will use the mean % SFA intake at baseline and 3 months from the two dietary recalls (Web-Q) which were collected both at baseline and follow up.

The primary analysis will test for:

- A difference in the change (from baseline to follow up) in % SFA intake between each intervention group compared to control;
- A difference in the change (from baseline to follow up) in % SFA intake between the two active intervention arms.

We will analyse the primary and secondary outcomes with a linear regression model with adjustment for practice and baseline values. Estimates of intervention effects will be reported with confidence intervals. All the tests will be done at a 5% two-sided significance level.

Steps for calculating %SFA from the WebQ output can be found in Appendix 1.

Handling missing data

The percentage and absolute withdrawal and participants lost-to-follow up will be reported for each study arm in the CONSORT flow-chart and reasons for missing data will be documented.

Within the final sample of participants that complete the study, it is possible that some participants only provide one dietary recall instead of two, this could happen at baseline and/or follow up. In this case, we will use one dietary recall for these participants in the primary outcome analysis.

For those who withdraw or who are lost to follow up, we will assess the sensitivity of the analysis to different assumptions about missing data using baseline observation carried forward which is a commonly used imputation method.

Handling outliers

It is possible that some participants' dietary intakes for a specific day may be deemed "implausible" because they have reported too much or too little energy to be considered a measure of habitual intake. Many studies exclude participants with implausible energy intakes using cutoffs for plausible energy intakes, allowing for some under- and overreporting. These cutoffs are defined as less than

500 kcal/day and greater than 3,500 kcal/day[1]. For the primary analysis, outliers will be included and a sensitivity analysis will be conducted by excluding these outliers based on the above cutoffs.

MULTIPLE COMPARISONS AND MULTIPLICITY

As we are planning to conduct pairwise comparisons in the primary outcome we will use a suitable method to adjust p values to account for multiplicity (Tukey method or equivalent).

MODEL ASSUMPTIONS

The appropriateness of the normality, no outliers, and homogeneity of variances assumptions required for the 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.

SECONDARY ANALYSIS

SECONDARY OUTCOMES

Between each trial arm and control, linear regression models will be used to test for:

1. From dietary intake measurements: a difference in the change (from baseline to follow up) in absolute amount of SFA (kcal) and in the intake (frequency) of high SFA food groups (e.g. products with >1.5 grams of SFA per 100 grams of the product) and low SFA food groups (e.g. products with ≤1.5 grams of SFA per 100 grams of the product).
2. From food purchases: a difference in the change (from baseline to follow up) in SFA from total purchases (% from energy purchased, kcal per £ spent); and in volume of purchases (g) of food items with low SFA (e.g. products with ≤1.5 grams of SFA per 100 grams of the product) and high SFA (e.g. products with >1.5 grams of SFA per 100 grams of the product);
3. From clinical measurements: a difference in the change (from baseline to follow up) in LDL-cholesterol, HDL-cholesterol, total cholesterol, non-HDL cholesterol, total cholesterol/HDL ratio and triglycerides;

NON-EFFICACY OUTCOMES

Between each trial arm and control, linear regression models will be used to test for:

1. From dietary intake measurements: a difference in the change (from baseline to follow up) in energy intake (kcal), total fat (%, kcal), total sugars (%, kcal), fibre (g per 1000kcal) and salt (g per 100g) using 2 x 24h WebQ dietary recalls.
2. From food purchases: a difference in the change (from baseline to follow up) in energy density (kcal per g purchased), total fat (% kcal purchased, kcal per £ spent), sugar (% kcal purchased, kcal

[1] Comparison of Methods to Account for Implausible Reporting of Energy Intake in Epidemiologic Studies
Jinnie J. Rhee Laura Sampson Eunyoung Cho Michael D. Hughes Frank B. Hu Walter C. Willett. American Journal of Epidemiology, Volume 181, Issue 4, 15 February 2015, Pages 225–233.

per £ spent), fibre (g per 1000 kcal purchased) and salt (g per 100g purchased); mean total cost of the shopping basket (£).
3. From clinical measurements: A difference in the change (from baseline to follow up) in systolic and diastolic blood pressure (mmHg); and a difference in the change (from baseline to follow up) in body weight (absolute (kg) and relative (%)).

Feasibility and Process measures

- Recruitment rates: we will report the number of participants who accept the invitation, consent to take part in the study and are randomised at baseline.
- Follow-up rates: we will report the number of participants who return for the follow up visit at 3 months
- Acceptability and views of the intervention: we will use the questionnaires collected at baseline and at follow up. The open-ended follow-up questions will be analysed using content analysis in MS Excel.
- Other process measures: this also includes the qualitative data from the questionnaires collected at baseline and at follow up. In addition, we will use the shopping data obtained during the study to look at the number and types of swaps purchased after receiving their intervention, as well as the total amount of money spent per week and month at Tesco. Fidelity of the intervention will be also evaluated using the data collected around the number of swaps sent to participants, the duration and content of the brief advice session, as well as the time gap between the baseline appointment and the intervention session.

Qualitative Sub-study

Verbatim transcriptions will be analysed using the NVivo 11 software programme. A thematic analysis approach will draw out themes, categories and nodes from the data pertaining to the (i) knowledge, (ii) perceived barriers and facilitators, (iii) contextual influences, and (iii) value of the healthcare advice provided. One researcher will deductively code the transcript data against an initial thematic framework using the Framework Method, which comprises five steps: (i) familiarisation, (ii) developing a thematic framework, indexing, charting, mapping and interpretation.

A second researcher will check a sub-sample of 10 percent for validity and inter-rater reliability. In instances where it is unclear how to code themes against the initial framework, discussion with a third reviewer will reach consensus on whether to form a new theme or whether to expand an existing theme.

Thematic coding will begin once data collection starts in a process of iterative data gathering and analysis i.e. a zigzag approach. Early analysis will inform further data gathering. For this reason, the topic guide will be subject to ongoing review and edits if unexpected themes begin to emerge. Findings will be synthesised narratively.

SENSITIVITY ANALYSES

Sensitivity analyses will be conducted as follows:

- Using baseline observation carried forward for those people with missing information at follow up.
- Excluding participants with only one dietary recall at baseline or follow up to account for the fact that these participants will not have a real measure of "usual" intake if they only have 1 dietary recall
- Including data from the WebQ which appear to have implausible daily energy intakes based on the recommended cutoffs: <500 kcal/day and >3,500 kcal/day.
- Excluding participants who received their intervention a month and half after the date of the baseline visit: this is to account for the fact that their engagement with the study may have affected the outcomes;
- Excluding participants who changed their lipid lowering medication during the study: this is to avoid detecting an effect which is due to the medication and not by the intervention provided;
- For analyses of purchasing patterns where we need to use transaction data, we will exclude those participants which are not considered "loyal" shoppers as per inclusion criteria (shopping mainly at Tesco (e.g. at least once/week instore and/or online)) and/or with a minimum expenditure of £25/week for a single person household.

SUBGROUP ANALYSES

Using the appropriate interaction terms in the above mentioned models, we will perform subgroup exploratory analyses of the primary and secondary outcomes by sociodemographic characteristics (SES) using participant's education, as a previous study has shown that lower SES households purchase a higher proportion of energy from less healthy foods with smaller but important differences in the SFA content from purchased foods which may lead to differential effectiveness. While the study is not powered to look for such effects here, this information will inform planning of subsequent research.

ADDITIONAL EXPLORATORY ANALYSIS

We will conduct exploratory analysis by gender, BMI stratified into <30 and ≥30kg/m^2 groups provided we have sufficient numbers within each subgroup ($n \geq 30$).

VALIDATION

A senior statistician will double check the analysis plan and will code the analysis for the primary analysis. The senior statistician will oversee the analysis of the secondary outcomes and exploratory analyses.

APPENDICES

Appendix I. Steps for calculating mean %SFA from the WebQ output

Each participant has provided 4 Web Qs, two at baseline (day 1 and 2) and two at follow up (day 3 and 4). All participants (n=113) provided day 1 and 2, but some participants only provided day 3 (n=106) and day 4 (n=101), either because they were lost-to-follow up (n=7) or because they did not complete the questionnaire properly (n=5).

The following variables will be used for the primary outcome analysis:

- Id
- Group
- Day
- SFA
- Energy

The following steps will be used to calculate %SFA:

1. Convert SFA intake from grams to kcal

The variable "SFA" is given in grams. We need to convert this variable to kcal by multiplying it by 9 (the amount of energy in kcal per gram of fat). The variable "energy" is given in kJ. We need to convert this variable to kcal by multiplying by 0.239006 (the amount of kcal per kJ).

In order to calculate %SFA, the variable "SFA" in kcal will be divided by "energy" in kcal and this will be multiplied by 100.

This same calculation will apply to the other nutrients to be analysed as secondary outcomes using 4 kcal per gram for carbohydrates and protein.

2. Obtain mean intakes across the 2 days collected at baseline and follow up

We will calculate the mean %SFA for day 1 and 2 (baseline) and the same for day 3 and 4 (follow up).

3. Calculate the difference between baseline and follow up

The mean differences in %SFA between baseline and follow up will be compared across the intervention groups and the control.

Appendix 2. Template tables for presentation of results

Baseline characteristics of participants

N(%), unless otherwise specified	Control (n=)	Brief Advice (n=)	Brief +Shopping Advice (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)			
Blood pressure, mean (SD)			
Smoking			
Current			
Ex-smoker			
Never			
Alcohol units/week, median (IQR)			
Ethnic group			
White			
Black / Asian			
Mixed / Other			
Education			
No formal qualifications			
Secondary education			
Higher education			
Household size, median (IQR)			
Household supermarket spending, median (IQR)			
Weekly grocery shopping >£25/trip			
≥ Once a week			
Once a week			
Once a fortnight			
Once a month			
< Once a month			
Relevant Health history			
CVD			
High blood pressure			
Diabetes			
AF			
CKD			
Relevant medications			
Statins			

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

		Mean change ± SE				Between group difference (95% CI)		
	Baseline values Mean (SD)	Control (n=)	Brief Advice (n=)	Brief +Shopping Advice (n=)		Brief Advice vs Control	Brief +Shopping Advice vs Control	Brief Advice vs Brief +Shopping Advice
Primary Outcome								
SFA (% EI)								
Secondary Outcomes								
Food intake								
SFA intake (kcal)								
Intake of products ≤1.5% SFA (freq)*								
Intake of products >1.5% SFA (freq)*								
Food purchases								
SFA (% of kcal purchased)								
SFA (kcal per £ spent)								
Volume of products with ≤1.5% SFA (g)*								
Volume of products with >1.5% SFA (g)*								
Blood lipids (mmol/L)								
LDL-cholesterol								
HDL-cholesterol								
Total cholesterol								
Triglycerides								
Non-HDL cholesterol								
Total cholesterol/HDL ratio								

*We will also report this for different food groups which are top sources of SFA, including cakes/biscuits, meat, dairy, spreads, salty snacks, among others.

Non-efficacy outcomes between trial arms, all mean± SE

		Mean change ± SE				Between group difference (95% CI)		
	Baseline values Mean (SD)	Control (n=)	Brief Advice (n=)	Brief+Shopping Advice (n=)		Brief Advice vs Control	Brief+Shopping Advice vs Control	Brief Advice vs Brief+Shopping Advice
Food intake								
Total energy intake (kcal)								
Total fat (% EI)								
Total fat (kcal)								
Total sugar (% EI)								
Total sugar (kcal)								
Fibre (g/1000 kcal)								
Salt (g/100g)								
Food purchases								
Energy density (kcal/g purchased)								
Total fat (% kcal purchased)								
Total fat (kcal per £ spent)								
Total sugar (% kcal purchased)								
Total sugar (kcal per £ spent)								
Fibre (g/1000 kcal purchased)								
Salt (g/100g purchased)								
Basket cost (£)								
Other clinical outcomes								
Systolic blood pressure (mmHg)								
Diastolic blood pressure (mmHg)								
Weight (kg)								
Weight (%)								

Process measurement and feasibility outcomes

N(%), unless otherwise specified	Total (n=)	Control (n=)	Brief Advice (n=)	Brief +Shopping Advice (n=)
Recruitment Rates				
Number of participants invited				
Number of participant consented				
Number of participant randomised				
Follow up Rates				
Number of participants measured at FU				
Swap and shopping behaviours				
Number of swaps from those offered purchased over the intervention period				
Proportion of swaps accepted out of those offered over the intervention period				
Number of swaps from those offered purchased over the intervention period by food group**				
Total money spent per month (£)				
Fidelity of the intervention				
Number of shopping reports sent				
Number of days between baseline and intervention session				
Number of core components mentioned during the brief advice session				
Duration of the brief advice session				

** Food groups may include cheese, spreads, milk, meat, cakes and biscuits, salty snacks, among others*

*** Intervention acceptability, attitudes, knowledge and feedback collected from participant facing questionnaires and the qualitative study will be reported descriptively and narratively*