Nudging healthier dietary habits: evaluation of a supermarket placement strategy in the WRAPPED study

Short title: WRAPPED 2

Protocol for a discount supermarket intervention with a prospective matched controlled cluster design that aims to improve food purchasing and dietary behaviours of women customers

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SPONSOR

The University of Southampton is the research sponsor for this project. For further information regarding sponsorship conditions, please contact Christina Vogel (contact details above).

COLLABORATOR

The supermarket chain involved in this study is a non-financial collaborator who will implement the intervention and provide the study team with participant loyalty card data and store sales data for the evaluation to be completed. Participant purchasing data will only be shared after a participant has provided explicit consent to the supermarket chain for their loyalty card data to be shared with the study team for the nine month study period and to be used for the purpose of this study.

FUNDING

Funding for this study has been received from the NIHR Public Health Research (PHR) programme, NIHR Southampton Biomedical Research Council and Medical Research Council.

GENERAL INFORMATION

This protocol describes the WRAPPED study and provides information about the procedures for identifying study stores, recruiting participants and for running the study. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known co-applicants, collaborators and funders of the study as necessary. Problems relating to the study should be referred, in the first instance, to the study manager.

COMPLIANCE

This study will adhere to the conditions and principles outlined in the EU Directive 2001/20/EC, EU Directive 2005/28/EC and the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95). It will be conducted in compliance with the protocol, the Research Governance Framework for Health and Social Care (Department of Health 2nd July 2005), the General Data Protection Regulations 2018, Mental Capacity Act (2005), and other regulatory requirements as appropriate.

TABLE OF CONTENTS

0. PROJECT SYNOPSIS 6

1.1 BACKGROUND INFORMATION 11
1.1.1 EXISTING KNOWLEDGE 11
1.1.2 JUSTIFICATION FOR THE STUDY 12
1.1.3 THE INTERVENTION 13
1.1.4 DESCRIPTION OF THE POPULATION TO BE STUDIED 14
1.1.5 SUMMARY OF THE KNOWN AND POTENTIAL RISKS AND BENEFITS, IF ANY, TO HUMAN SUBJECTS. 14
1.1.6 STATEMENT OF COMPLIANCE 14

2. RESEARCH OBJECTIVES 16

2.1 STUDY OBJECTIVES 16
2.1.1 PRIMARY OBJECTIVE 16
2.1.2 SECONDARY OBJECTIVES 16

3. STUDY DESIGN 16

3.1 STUDY DESIGN 16
3.2 NUMBER OF CENTRES INVOLVED 16
3.3 STUDY STORE SELECTION 16

4. SELECTION AND WITHDRAWAL OF PARTICIPANTS 18

4.1 INCLUSION AND EXCLUSION CRITERIA 18
4.1.1 INCLUSION CRITERIA 18
4.1.2 EXCLUSION CRITERIA 18
4.2 WITHDRAWAL CRITERIA 18

5. ASSESSMENTS AND SAFETY 18

5.1 ASSESSMENT PROCEDURE 18
5.2 EFFECTIVENESS 18
5.3 ASSESSMENT OF HARMS 18

6. OUTCOME MEASURES 18

6.1 PRIMARY OUTCOME MEASURES 18
6.2 SECONDARY OUTCOME MEASURES 19
6.2.1 DIETARY QUALITY 19
6.2.2 DAILY FRUIT AND VEGETABLE INTAKE 19
6.2.3 STORE SALES OF FRUIT AND VEGETABLES 19
6.2.4 ECONOMIC EVALUATION 20

7. STUDY PROCEDURES AND DATA COLLECTION 20

7.1 RECRUITMENT 20
7.2 CONSENT 21
7.3 OUTCOME DATA COLLECTION 22
7.4 PARTICIPANT INCENTIVES 22
7.5 PROCESS EVALUATION 23
7.5.1 INTERVENTION IMPLEMENTATION 23
7.5.2 MECHANISMS OF INTERVENTION IMPACT 23
7.5.3 INTERVENTION CONTEXT 24
7.6 DATA COLLECTION CLOSURE 25

8. STATISTICS 25

8.1 SAMPLE SIZE 25
8.2 STATISTICAL ANALYSIS 25
8.3 ECONOMIC ANALYSES 26
8.3.1 INDIVIDUAL PERSPECTIVE 26
8.3.2 RETAILER PERSPECTIVE 26
8.3.3 SOCIETAL PERSPECTIVE 27
8.4 QUALITATIVE DATA ANALYSES 27

9. GOVERNANCE AND STUDY MANAGEMENT 28

9.1 SPONSOR 28
9.2 FUNDING 28
9.3 STUDY MANAGEMENT 28
9.4 DATA MONITORING AND QUALITY ASSURANCE 28
9.5 INSURANCE AND INDEMNITY 28

10. ETHICAL ARRANGEMENTS 28

10.1 ETHICAL APPROVAL 28
10.2 STATEMENT OF CONFIDENTIALITY 29

11. DATA HANDLING, SHARING AND STORAGE 29

12. PUBLICATION PROCEDURE 30

REFERENCES 30

0. PROJECT SYNOPSIS

Full title:	Nudging healthier dietary habits: evaluation of a supermarket placement strategy in the WRAPPED study
Sponsor:	University of Southampton
Principal Investigators	Dr Christina Vogel Professor Janis Baird
Co-Applicants	Dr Sarah Crozier Professor Cyrus Cooper Professor Graham Moon Professor Janet Cade Professor Joanne Lord Professor Kylie Ball Dr Wendy Lawrence
Funders:	NIHR Public Health Research programme UK Academy of Medical Sciences NIHR Southampton Biomedical Research Council Medical Research Council
Funder Ref No:	17/44/46
Key words:	Choice architecture, supermarkets, diet, purchasing, women, inequalities
Study design:	Natural experiment with prospective matched controlled cluster design
Primary Objective:	To assess whether increasing availability of fresh fruit and vegetables and positioning them at the front of the store in discount supermarkets improves fresh fruit and vegetable purchasing patterns after 6 months amongst women customers aged 18-60 years compared to control customers
Secondary Objectives:	1. To assess effect modification by educational attainment on women's change in fruit and vegetable purchasing. 2. To assess how the intervention affects women's dietary quality and daily fruit and vegetable intake, and the dietary quality of their young children. 3. To assess how the intervention influences weekly store sales of fruit and vegetables. 4. To conduct an economic evaluation from individual, retailer and societal perspectives. 5. To conduct a detailed process evaluation to examine: i) intervention implementation in each store and the exposure and reach to participants, ii) mechanisms of intervention impact by exploring the experiences of participants and staff and, iii) how contextual factors, such as social influences, spatial access to supermarkets and government policy, influence intervention effects.
Rationale:	Unhealthy diet is a key modifiable risk factor for non-communicable diseases (NCDs) and the cost of poor diet-related ill health to the NHS is £5.8 billion annually. Government policy has placed increasing emphasis on improving poor diet through choice architecture initiatives that alter micro-environments where people make food choices. The premise of these initiatives is that much human behaviour is automatic, cued by environmental stimuli that can influence the behaviour of many people simultaneously. Supermarkets are a major source of food for many families yet understanding of how the environment within supermarkets influences food choices is limited. Evaluating choice architecture strategies that could enable families, particularly those from disadvantaged backgrounds, to make healthy food choices is important to improve public health now and in the future.

	This research project aims to address a gap in understanding about the micro-environmental determinants of diet and who responds to food product placement nudge interventions by exploring whether improving the positioning and increasing the availability of fresh fruit and vegetables in discount supermarkets influences the purchasing and dietary patterns of women aged 18-60 years and whether it is cost effective.
Study Setting:	The study setting is discount supermarkets across England.
Intervention:	The intervention for this study increases the availability and enhances the position of fresh fruit and vegetables in discount supermarkets. The intervention involves the creation of an expanded fresh fruit and vegetable section, positioned at the store entrance of intervention stores. This intervention creates a healthier in-store layout and has potential to benefit public health. The control condition is the previous store layout with a limited range of fresh fruit and vegetables, placed at the back of the store. Control and intervention stores will be located across England to improve generalizability of the sample. This intervention forms part of a discount supermarket chain's store refurbishment programme. Randomisation of stores is not viable within the company's business model. The control stores will be matched to an intervention store on: i) sales profile (total weekly sales and percentage of produce sold), ii) customer profile (age and gender), and iii) neighbourhood deprivation (IMD deciles) in order to reduce differences between control and intervention stores. Matching control stores on these factors increases the similarity of intervention and control stores and reduces effects of confounding. This method proved successful in the pilot phase, showing no difference in demographic characteristics between intervention and control participants (all $p<0.05$).
Inclusion Criteria:	Women aged 18-60 years, who hold a loyalty card and shop in a study store. Shoppers who choose items in-store but opt for home delivery will be eligible.
Exclusion Criteria:	Women under the age of 18 or over 60 years, irregular shopper or online-only shopper, do not hold a loyalty card.
Total No. of Sites:	The study will be conducted by researchers working at the MRC Lifecourse Epidemiology Centre (LEC), University of Southampton. The 18 intervention and 18 control stores will be located across England.
Study Duration:	~4 years (March 2019 – February 2023)
Data Collection Duration:	March 2019 – November 2022
Biological Samples:	None
Number of Participants:	This study will recruit 216 intervention and 216 control participants (9 from each of the 24 intervention and 24 matched control stores).
Primary Outcome:	The primary outcome is change in participant's weekly fruit and vegetable purchasing patterns from baseline (3 months prior to refurbishment) to the 3-6 month period post-refurbishment. Change in fruit and vegetable purchasing from baseline to the 0-3 month period post-refurbishment will also be assessed to measure short-term purchasing effects.

Secondary outcomes:	Secondary outcomes of the study include: - women's dietary quality, - women's daily fruit and vegetable intake - women's level of educational attainment (effect modifier) - young children's dietary quality - weekly store sales - Economic evaluation data from individual, retailer and societal perspectives.
Sample size:	The study will be powered to detect differences in the primary outcome (fresh fruit and vegetable purchasing) between women in the intervention and control groups during the 3-6 months post-intervention. We used data from our previous research on women in Hampshire and considered the supermarkets at which the women shopped as clusters to estimate a rho of 0.1 as our intraclass correlation coefficient. We will aim to detect a difference of 0.3 items (1.5 portions) per week. Assuming a standard deviation of 0.7 items (3.5 portions) per week, 24 stores in each arm and 9 women per store provides 90% power at a 5% significance level (2-sided).
Participant Recruitment and Consent:	Women aged 18 to 60 years, who hold a supermarket chain loyalty card and shopped at least once in a study store in the 12 weeks prior to recruitment will be sent an invitation and information letter. The letter will be sent by the supermarket chain to comply with privacy laws. In-store recruitment will also be used, whereby members of the research team approach women customers while shopping and provide them with a study information sheet. Women register their interest with the researcher in-store and are phoned at suitable time for them to be consented. Both intervention and control participants will be recruited using these methods. All participants will be offered up to £30 Love2Shop vouchers for participating in the study. Potential participants who register their interest with the study team will be contacted by phone from a study team member to: i) check their eligibility for participation, ii) ensure the participant has received an information letter, iii) confirm the conditions of consent, and iv) book an appointment for the baseline telephone interview when consent will be obtained. To ensure compliance with data protection laws, participants who have consented with the study team and completed the baseline survey will be sent an email from the retailer to seek each participant's consent for the retailer to share their loyalty card data with the study team. Separate invitations, and consent, to participate in qualitative interviews and have the interview voice recorded will be issued, and obtained, from all those taking in part in the process evaluation qualitative interviews. A final wave of recruitment will be conducted before the study completion to boost participant numbers to enhance power for primary outcome (changes in weekly fruit and veg purchasing patterns). This will include approaching eligible customers of the existing study stores who have not already participated in the study asking them to share their retrospective loyalty card data and recontacting our study participants who have provided dietary data but not consent for accessing their purchasing data, asking them to share their retrospective loyalty card data.

Outcome Data Collection Methods:	Members of the study team will administer questionnaires via telephone to participants in the 8 weeks before refurbishment, and 1, 3 and 6 months post-intervention. The questionnaire was tested in the pilot phase and will collect data about women's demographic characteristics and secondary outcome data including women's dietary behaviours (and their young child's aged 2-6 years if relevant), perceptions of their supermarket's in-store environment, food shopping habits and psychological and social factors. Distribution of participant incentives follows 1x £10 Love2Shop voucher after completion of baseline, 3 and 6 month questionnaires. The costs and distribution of these vouchers will be covered by the study team. Following the receipt of informed consent from each participant, the supermarket chain will share each consenting participant's complete weekly sales data obtained through the loyalty card scheme covering the 3 months before refurbishment, plus the 0-3 and 3-6 months post-refurbishment. Information about purchases, stores visited, number of visits per week, and total spend per week will be provided by the supermarket chain at the end of the 9 month study period for participants from each pair of intervention and control stores. Complete weekly store sales data will be provided from the supermarket chain's electronic sales data records for the same periods as the individual data. Economic evaluation will be conducted from individual, retailer and societal perspectives. Individual perspective evaluation will use participant survey data for food expenditure, time spent food shopping, as well as travel costs to and from supermarkets; these data will be supplemented by loyalty card data. Retailer perspective evaluation aims to assess factors likely to influence supermarket decisions about investments in food product and placement strategies similar to the intervention in this study. Retailer costs will be estimates generated through discussion with supermarket staff and may include: cost and expected lifespan of previous store refurbishment (including capital costs and costs of store closure days for refurbishment), the costs and expected lifespan of current store refurbishment (fresh fruit and vegetable store entrance), ongoing costs such as additional refrigerator storage, extra produce deliveries (transport costs), produce waste costs, changes in product group sales (displacement, substitutions and complements) and staff costs at head office and store level. Results will be presented at an aggregated level to respect commercial confidentiality. The financial impact of changes in sales volumes will be estimated using publicly available information to reflect expected profit margins within the industry. Societal perspective costs will be estimated for resources associated with the capital investment and ongoing costs of the store refurbishment, changes in food expenditure, time and travel costs for individuals and health and social care costs for related health conditions. The sources of data for quantifying resource use associated with the intervention are similar as for the individual and retailer perspectives, but the principles of costing are rather different.
Process Evaluation Data Collection Methods:	A detailed process evaluation will be conducted, following MRC guidance on process evaluation. Intervention fidelity will be assessed in intervention and control stores through in-store surveys conducted by trained fieldworkers using published tools. Details about products placed at the front of the store before and during the intervention will be collected by fieldworkers via observation and telephone using a bespoke tool. Intervention exposure will be determined by calculating the number of shopping visits from loyalty card data and will be supplemented by reported

	frequency of visits to stores from participant surveys. Intervention reach will be assessed by combining individual purchasing data with demographic data to identify the characteristics of participants who increased their fruit and vegetable purchases and those who did not. Mechanisms of impact will be examined qualitatively through go-along interviews with a purposive subsample of participants (n=30, 15 per arm) and semi-structured interviews with a convenience sample of staff (n=20). These interviews will examine the interpretations participants assign to physical and social objects during everyday interactions and activities (i.e. food shopping) and offer insight into staff understanding of how placement strategies work to influence customers and the drivers and challenges for retailers in providing more healthful environments to customers. To examine intervention context we will collect detailed information about all the supermarkets participants visited in the previous month and conduct audits to assess the in-store environments of the most popular stores. The broader context will be assessed via semi-structured interviews with a purposive sample of policy makers, food retail representatives, researchers and non-government organisations working with food retailers to identify policy, retail business and macroeconomic factors that may have influenced intervention implementation or impact.
Statistical Methods:	We will perform an intention-to-treat analysis using use multilevel models, including 3-level models with women's weekly purchasing data clustered within women, who are clustered within stores. Our primary outcome will be the results at 6 month follow-up period with adjustment for the month baseline period included in the modelling. Confounders will be determined through the use of a Directed Acyclic Graph. Planned subgroup analyses will focus on whether there are different effects for level of educational attainment as a marker of disadvantage. The economic evaluation will be conducted from three perspectives: individual, retailer and societal. Individual and retailer results will be presented as simple cost-consequence analysis (CCA) tables, with estimates of monetary costs or savings shown in a 'balance sheet' alongside summary statistics for other relevant outcomes. For the societal perspective, we will conduct a cost-utility analysis (CUA), to assess the efficiency of the investment in store refurbishment in relation to future costs and savings to public and private bodies and health effects for the women, as well as the impact on health inequalities. Health effects and related treatment and care costs will be estimated using a Markov model. All process evaluation interviews will be transcribed verbatim and analysed thematically. Transcripts will be read and re-read and comments from participants and staff and coded into coding frames based on the themes. Confidentiality will be upheld and no details of individuals will be revealed.

1. INTRODUCTION

1.1 Background information

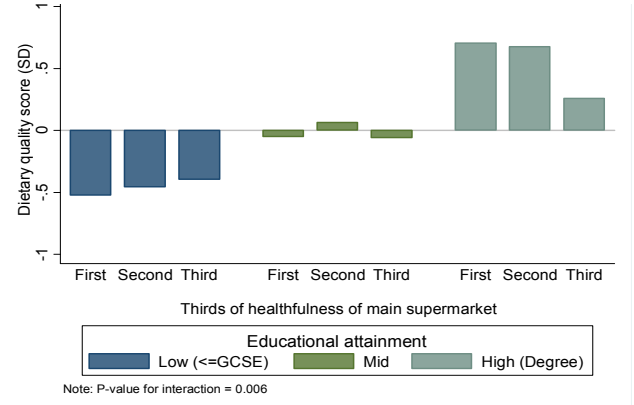
1.1.1 Existing knowledge

Non-communicable diseases (NCDs) and related conditions like obesity are the leading cause of adult morbidity and mortality in the UK. They are estimated to account for 89% of total deaths, with cardiovascular diseases alone contributing 31%.[1] Poor diet is the second leading risk factor for NCDs, responsible for 19% of deaths globally; low fruit consumption alone accounts for 4.3% of deaths.[2] The cost of poor diet-related ill health to the NHS is £5.8 billion annually[3] and as many as 42,000 deaths could be prevented each year if people ate more fruit and vegetables. Most adults in England consume too much salt, saturated fat and free sugar, and do not eat the recommended five daily portions of fruit and vegetables.[4] Among low-income groups these trends are more extreme.[5]

Systematic reviews have shown that interventions providing information about healthy dietary behaviours alone are largely ineffective among disadvantaged populations and that social marketing campaigns, such as '5-a-day', can increase dietary inequalities.[6, 7] Evidence for interventions that are effective for disadvantaged groups is limited, however those addressing the broader environmental determinants of diet are most promising.[8]

The dual-process model theorises that human behaviours, like food choice, result from a combination of i) reflective processes and ii) automatic processes.[9] Educational campaigns target reflective processes that require conscious awareness of motivations and actions. Automatic processes are unconscious reactions to environmental stimuli. The psychological agency required for reflective processes is lower among those who are disadvantaged and this difference may be contributing to dietary inequalities.[10, 11] UK research supports this notion and has shown that exposure to unhealthy food environments exacerbates dietary inequalities. In Cambridgeshire, associations between exposure to fast food outlets and fast food intake were most pronounced among adults of low socioeconomic status.[12] In Hampshire, our prior work (Vogel, Baird, Moon, Cooper) showed the diets of women with low educational attainment was more affected by less healthy supermarket environments than women with higher attainment (Figure 1).[13] Shopping at less healthy discount and small supermarkets, with poorer availability, pricing and placement of healthy foods,[14] was associated with poor dietary quality among women who left school aged 16 but not among those with degree qualifications. UK government policy recognises that more effort is needed to develop interventions to improve health equitably and supports using choice architecture initiatives to alter micro-environments, like supermarkets, where people's choices are largely governed by automatic processes.[15, 16]

Figure 1. The relationship between thirds of supermarket healthfulness and dietary quality by educational attainment



Choice architecture initiatives are non-financial and involve altering the properties or placement of objects like food.[17] They can affect the behaviour of many people simultaneously, having the potential to influence population level dietary choices. The typology of choice architecture includes two components of placement interventions: position and availability.[17] There is evidence from retail marketing research that positioning products in prominent locations, like the front entrance, end-of-aisle or islands, increases store sales.[18] Increasing the availability of, and displays for a product also enhances sales.[19] Recent systematic reviews of non-financial supermarket interventions promoting healthy food choices show efficacy of choice

architecture interventions.[20, 21] However, the majority of studies have assessed prompting strategies such as shelf labels, involved inadequate numbers of stores for a cluster design and had low to medium methodological quality.[22] Very few studies assessed the effect of product placement changes within stores, or the influence of nudge strategies on outcomes at the individual level (i.e. customers' purchasing and dietary patterns), with almost all assessing change at the store level.[21, 22] Not a single study reported on cost-effectiveness.[21]

Further high quality, adequately powered studies are needed to quantify the effect of choice architecture interventions in supermarkets. Studies that measure cost-effectiveness and examine differential effects by socioeconomic status are particularly important to inform future action. The WRAPPED (Women's Response to Adjusted Product Placement and its effects on Diet) study builds upon a successful collaboration that the study team have established with a UK discount supermarket chain. It provides a unique opportunity to evaluate, on a large scale, the effectiveness and cost-effectiveness of creating a healthier store layout in less healthy supermarkets frequently used by disadvantaged families.

1.1.2 Justification for the study

A quarter of all adult women in England are obese, and half of those aged 25-34 are overweight or obese.[16] This is the highest rate of all European Union member states and the greatest burden is borne by those who are socioeconomically disadvantaged.[23] Women remain household food gatekeepers dominating decisions about food shopping; 68% of women verses 32% of men reporting responsibility for all or most of food shopping tasks.[24] Women represent an important target group for improving the diets of the broader population. The short and long-term health of children, in particular, is influenced by their mothers' food choices.[25] The Scientific Advisory Committee on Nutrition expressed concern over the poor diets of young women in the UK and the impact on their children.[26] Improving the nutritional status of women before, during and after pregnancy is important for obesity prevention[16] and is a priority in UK policy (Healthy Lives Healthy People; The Health of the 51%: Women).[15, 16] Childhood obesity and poor diet are major UK public health problems and are likely to increase health inequalities in the future if not addressed. Identifying strategies that support women of childbearing age from disadvantaged backgrounds to make healthy food choices could improve public health now and in the future.

Almost 90% of UK grocery sales occur within supermarkets[27] and the subtle use of marketing techniques influences the food choices of an almost captive market. The majority of UK grocery market share held by the big supermarket chains is shrinking. Consumer use of discount supermarkets is growing rapidly with their grocery market share increasing by 12% between 2014 and 2017.[27] Small supermarket use is also increasing with customers shopping more often and buying more per visit.[28] However, discount and small supermarkets have less healthy in-store environments than other supermarkets, with lower availability and less prominent placement of fresh fruit and vegetables.[14] This is concerning because these types of stores are also used more regularly by disadvantaged families and younger adults who have poorer dietary behaviours.[13, 29] Systematic reviews of the association between supermarket environments and diet provide some evidence from the US that greater availability of healthy food is associated with healthier diet.[30, 31] Evidence from other high-income countries is equivocal and limited. Few studies have measured how placement strategies affect customers' food purchasing and dietary patterns.[32] Evaluating choice architecture initiatives that target marketing strategies in discount or small supermarkets would aid understanding of their effects among a population with the most to gain from dietary improvements.

Research using randomised controlled trial methods in supermarkets is limited, largely due to the complexity of undertaking research in this setting. Evaluating changes in supermarket layout is notoriously challenging due to differing health and business agendas. Individual randomisation for interventions altering in-store environments is difficult, and randomisation at the store level requires commitment that is problematic in this highly competitive, commercial setting. Natural experiments have proved a valuable method of assessing the effects of improved spatial access to supermarkets on diet.[33] We have developed a collaboration that allows us to undertake a natural experiment to evaluate a product placement intervention

in supermarkets. The collaborating supermarket chain has over 1000 stores in the UK and the store refurbishment programme that provides an opportunity to quantify the impact of a healthier store layout on the purchasing and dietary patterns of young women from deprived backgrounds.[29]

In 2016-2017 we undertook a pilot phase of this study with a prospective cluster controlled design. The aims of the pilot were to i) identify appropriate participant recruitment and retention methods, ii) test data collection and analysis methods and iii) assess feasibility of three intervention components. Women customers aged 18-60 years with a store loyalty card, who regularly shopped at one of 3 intervention or 3 matched-control stores were invited to participate. As is recommended during the pilot phase of a study,[34] a variety of recruitment strategies were trialled in order to identify those that are most effective including email, letter, SMS, shopping receipt note, Facebook advertisement, and in-store approach. Participants contacted the research team via text, email or Freephone and were consented by phone after eligibility was assessed. Participants completed four telephone surveys (baseline and 1, 3 and 6 months post intervention commencement) and were offered 3x £10 Love2Shop vouchers that were sent after completion of the baseline, 3 and 6 month surveys.

A total of 150 women (62 intervention and 88 control) were recruited (11%) to the pilot study, and 72 provided information about their child aged 2-6 years. A number of unsuccessful recruitment strategies trialled in the pilot will not be used in the full study. Successful recruitment methods were letters (49%) and in-store approach (34%). The rates for these strategies were better than those in previous supermarket trials which reported 21% response rate from postal letters[35] and 30% response rate from in-store approach.[36] Retention rates were high: 95% at 1 month, 92% at 3 months and 86% at 6 months. There was no difference in demographic characteristics between intervention and control participants (all $p>0.2$). Participants' median age was 36 years, 91% were white British, 59% had low educational attainment (≤GCSE), 68% lived in deprived areas (≤4 Index of Multiple Deprivation (IMD)) and 46% were in paid employment. Analysis of store sales and participant purchasing and dietary data from the pilot study indicate that an appropriately powered evaluation of a full trial to measure effectiveness and cost-effectiveness is required. The pilot study identified that a single-component intervention was feasible to evaluate in a full study. Implementing a single component intervention is scientifically advantageous because it enables assessment of the isolated effects of this particular placement intervention. Systematic reviews of supermarket interventions found the vast majority of studies to date have evaluated multi-component interventions in an effort to increase their impact. The reviews recommend that future studies assess isolated intervention effects to ensure efficient and cost-effective packaging of interventions.[21, 22]

1.1.3 The intervention

The collaborating supermarket has over 1000 stores nationwide and is often used by more disadvantaged families who tend to have poorer dietary and food purchasing patterns.[13, 29] The intervention is part of a refurbishment programme that increases the availability and enhances the positioning of fresh fruit and vegetables. Thus, this intervention incorporates both placement interventions from choice architecture typology: availability and position.[17] There is evidence that positioning products in prominent positions such as front entrance, end-of-aisle or checkout, increases their sales.[18] However, there is very little research assessing the effects of such strategies on individual purchasing or dietary patterns.[21]

Study stores will have sales profiles representative of the company spectrum and will generally be located in areas of higher deprivation. The intervention will be implemented throughout the year, excluding the Christmas retail period. The intervention will be implemented by the supermarket chain and we will follow the successful approach used in the pilot phase by working closely with head-office and store staff. The strong collaboration between the research team and supermarket head-office staff ensures that any unexpected issues can be promptly resolved. Refurbishment and staff training (on placement of products and fresh fruit and vegetable quality management) costs are being covered by the company.

The control condition is the previous layout of stores with a limited range of fresh fruit and vegetables, placed at the back of the store. Control and intervention stores will be located across England to improve generalizability of the sample.

Each participant's purchase locations will be tracked through their loyalty card data and information about other supermarkets used to purchase food will be obtained at each survey as a way of measuring contamination and level of exposure to the intervention or control conditions.

The logic model (Figure 1) specifies the research design, intervention components and the route of impact for the short, medium and long-term. The model specifies that disadvantaged women will be exposed to the in-store product placement changes which will increase their purchasing of fresh fruit and vegetables (short-term outcome) that in turn will improve their own and their young children's dietary quality (medium-term outcomes) and subsequently reduce inequalities in diet and obesity (long-term outcomes). This study will assess the short- and medium-term outcomes.

1.1.4 Description of the population to be studied

The target population is women, aged 18 to 60 years from disadvantaged backgrounds. There is considerable evidence that improving the diets of women in this age group will improve their own health, and the short and long-term health of their children.[25] Women are also primarily responsible for domestic food-related tasks that influence their partners and families' diets.[37]

1.1.5 Summary of the known and potential risks and benefits, if any, to human subjects.

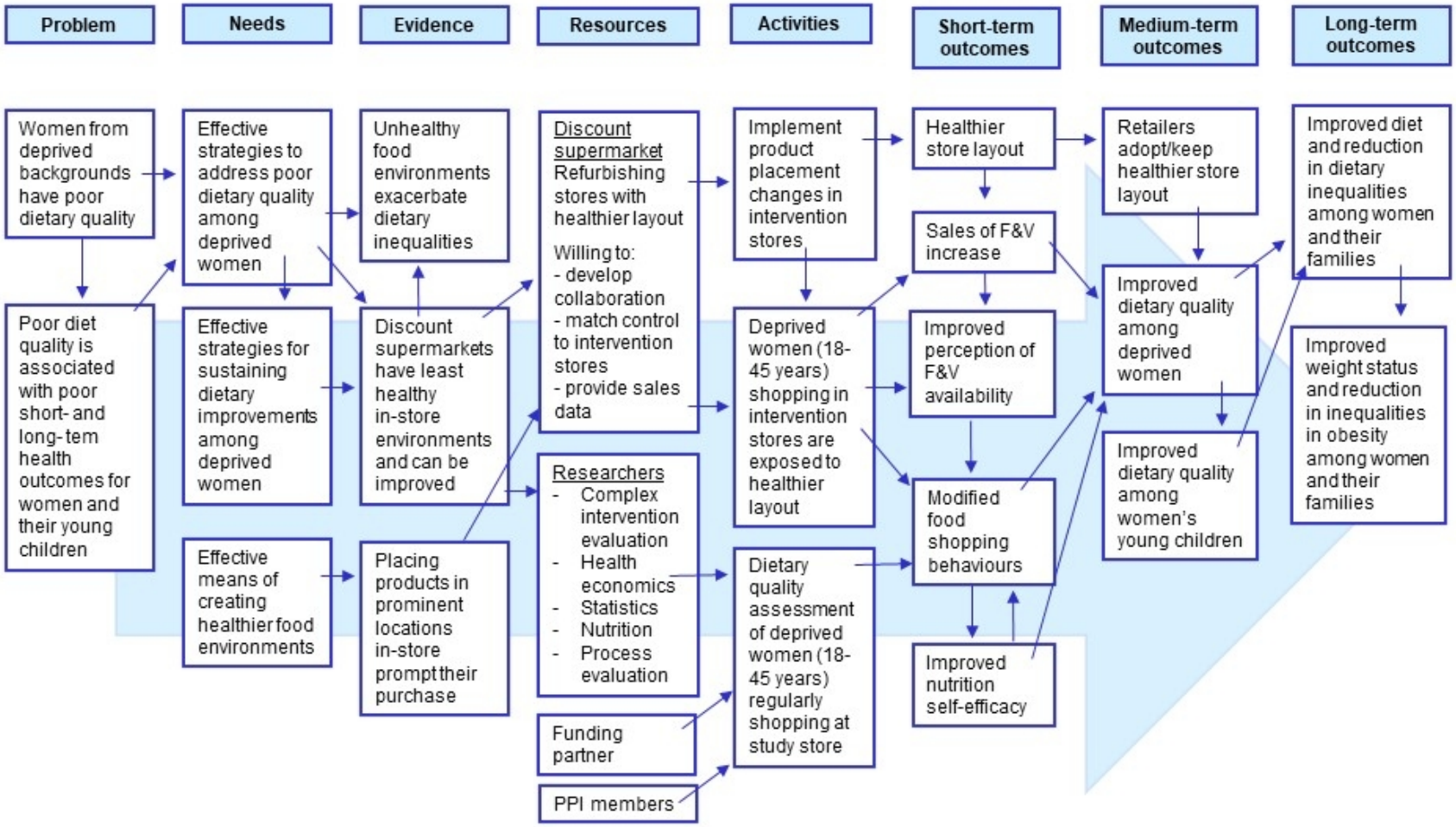
This study provides a number of benefits. First, the potential cost-saving to the NHS through improving the diets and health of women of childbearing age from disadvantaged backgrounds; it is known that even small increases in fruit and vegetable intake (0.3-1.0 portion/day) could reduce risk of later coronary heart disease by 4% and stroke by 5%. Second, collecting primary and secondary outcome data at the individual level will provide greater understanding of which individuals are susceptible to nudge interventions. Third, this study is founded on a unique relationship with a UK supermarket chain that has been cemented through the pilot study which identified effective study methods and secure data sharing arrangements. Fourth, participants reported personal benefits from taking part in the pilot phase including enjoying interaction with the research team, feeling good that their contributions could help others and being valued by financial reward.

The risks of this study are perceived to be low. Participant distress has been minimised through the use of validated measures in study questionnaires and reassuring participants that there are no 'correct' answers and that they can withdraw at any time without reason. Threats to engagement have been minimised by the undertaking of the pilot phase, which identified the most successful recruitment and retention strategies, these successful methods will be used in the full study. Data security risks in this study are limited and will be minimised by adherence General Data Protection Regulation 2018 and Freedom of Information Act 2000. Data will be stored on password-protected secure systems and access will be strictly controlled by the study PIs and MRC LEU Data Manager. Explicit consent to collect and use study data will be obtained. In particular, participant loyalty card purchasing data will be provided to the study team by the supermarket chain only after a participant has explicitly consented via email to the supermarket for their data to be shared. Transfer of data between the study team and collaborators will take place only through secure servers, using encryption software or personal transfer through trusted personnel.

1.1.6 Statement of compliance

This study will be conducted in compliance with the protocol, Good Clinical Practice requirements, Declaration of Helsinki and data protection laws.

Figure 1. **Women's Responses to Adjusted Product Placement and its Effects on Diet (WRAPPED)** - Logic Model



2. RESEARCH OBJECTIVES

2.1 Study Objectives

2.1.1 Primary objective

To assess whether increasing availability of fresh fruit and vegetables and positioning them at the front of the store in discount supermarkets improves fresh fruit and vegetable purchasing patterns after 6 months amongst women customers aged 18-60 years compared to control customers.

2.1.2 Secondary objectives

1. To assess effect modification by educational attainment on women's change in fruit and vegetable purchasing.
2. To assess how the intervention affects women's dietary quality and daily fruit and vegetable intake, and the dietary quality of their young children.
3. To assess how the intervention influences weekly store sales of fruit and vegetables.
4. To conduct an economic evaluation from individual, retailer and societal perspectives.
5. To conduct a detailed process evaluation to examine: i) intervention implementation in each store and the exposure and reach to participants, ii) mechanisms of intervention impact by exploring the experiences of participants and staff and, iii) how contextual factors, such as social influences, spatial access to supermarkets and government policy, influence intervention effects.

3. STUDY DESIGN

3.1 Study design

WRAPPED is a natural experiment with a prospective matched controlled cluster design (flow chart Figure 2).

3.2 Number of centres involved

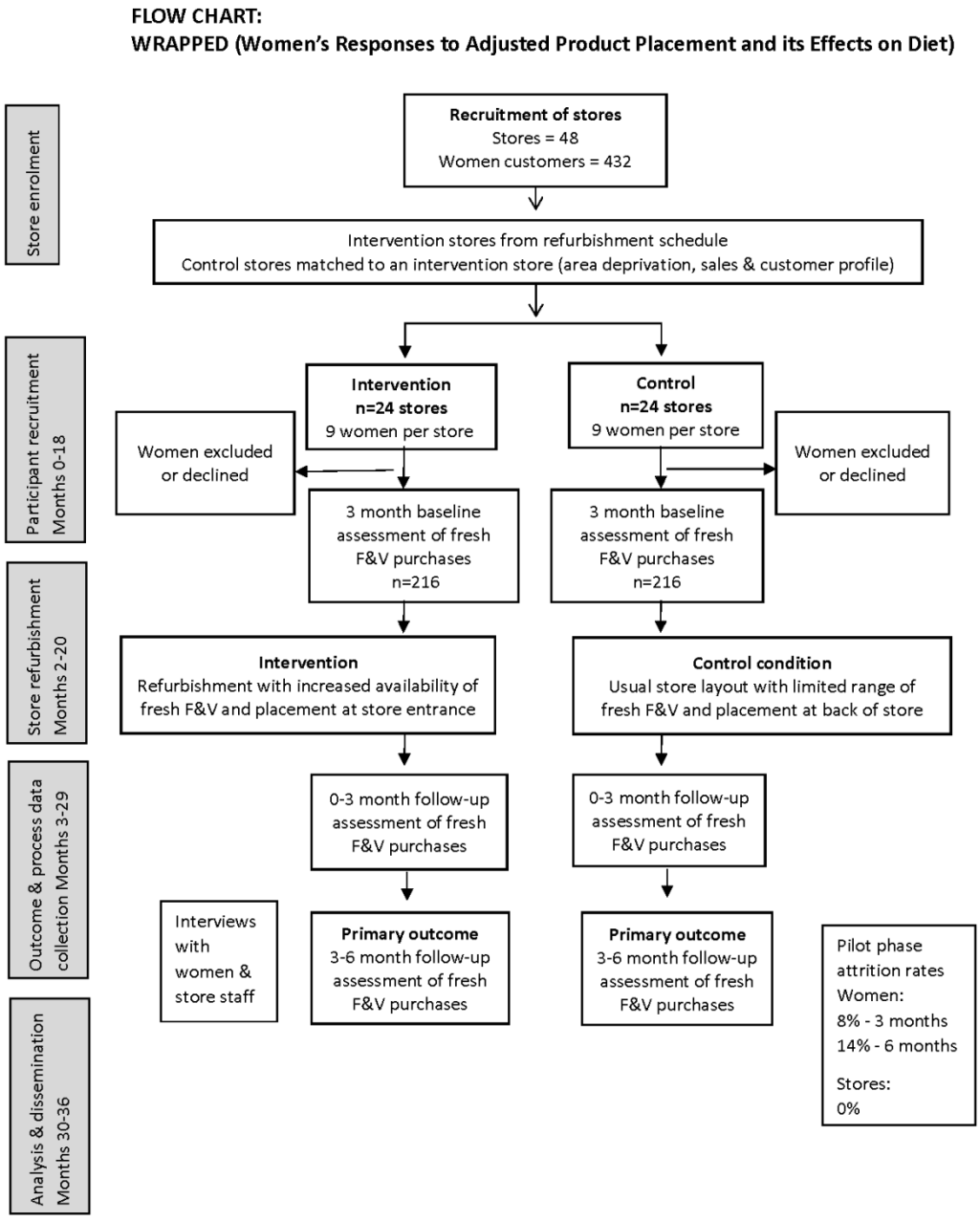
This is a single centre study, with all evaluations undertaken at MRC LEC, University of Southampton.

3.3 Study store selection

This study will sample 24 intervention and 24 control stores located in England, and 9 women customers will be recruited from each study store; allocation to treatment group will be at the store level (216 women in each group). Intervention stores form part of the collaborating supermarket's refurbishment programme. Each month, across the duration of the project, the refurbishment programme will be assessed for eligible intervention stores.

Randomisation of stores is not viable within the company's business model. Consequently, control stores will be matched to an intervention store on: i) sales profile (total weekly sales and percentage of produce sold), ii) customer profile (age and gender), and iii) neighbourhood deprivation (IMD deciles) in order to reduce differences between control and intervention stores. Matching control stores on these factors increases the similarity of intervention and control stores and reduces effects of confounding. This method proved successful in the pilot, showing no difference in demographic characteristics between intervention and control participants (all $p>0.2$). We will seek to select control stores located at least 20 miles from an intervention store to avoid contamination.

Figure 2.


FLOW CHART:
WRAPPED (Women's Responses to Adjusted Product Placement and its Effects on Diet)
Store enrolment
Participant recruitment Months 0-18
Store refurbishment Months 2-20
Outcome & process data collection Months 3-29
Analysis & dissemination Months 30-36
Recruitment of stores
Stores = 48
Women customers = 432
Intervention stores from refurbishment schedule
Control stores matched to an intervention store (area deprivation, sales & customer profile)
Intervention
n=24 stores
9 women per store
Control
n=24 stores
9 women per store
Women excluded or declined
Women excluded or declined
3 month baseline assessment of fresh F&V purchases n=216
3 month baseline assessment of fresh F&V purchases n=216
Intervention
Refurbishment with increased availability of fresh F&V and placement at store entrance
Control condition
Usual store layout with limited range of fresh F&V and placement at back of store
0-3 month follow-up assessment of fresh F&V purchases
0-3 month follow-up assessment of fresh F&V purchases
Interviews with women & store staff
Primary outcome
3-6 month follow-up assessment of fresh F&V purchases
Primary outcome
3-6 month follow-up assessment of fresh F&V purchases
Pilot phase attrition rates
Women:
8% - 3 months
14% - 6 months
Stores:
0%

4. SELECTION AND WITHDRAWAL OF PARTICIPANTS

4.1 Inclusion and exclusion criteria

4.1.1 Inclusion criteria

Women aged 18-60 years, who hold a loyalty card with the study supermarket chain and have shopped in a study store in the 12-weeks before recruitment according to loyalty card data. Shoppers who choose items in-store but opt for home delivery will be eligible.

4.1.2 Exclusion criteria

Women under the age of 18 or over 60 years, do not hold a loyalty card or online-only shopper.

4.2 Withdrawal criteria

Participants can withdraw at any point without giving a reason. All contact details for the participant will be deleted immediately and no further data will be collected from that participant. Participants can request for all their data to be deleted, however, data that have already been anonymised, amalgamated and published cannot be deleted.

5. ASSESSMENTS AND SAFETY

5.1 Assessment procedure

Individual weekly fresh fruit and vegetable purchasing (primary outcome) and weekly store sales (secondary outcome) will be obtained from electronic sales data and will cover: 3 months before refurbishment, plus 0-3 and 3-6 months post-refurbishment. Other secondary outcomes (dietary quality and fruit and vegetable intake) will be collected via telephone surveys administered by the research team at baseline (prior to intervention commencement), and 1, 3 and 6 months after intervention implementation. Data collection for sales and survey data will occur concurrently for each pair of intervention and matched control stores.

5.2 Effectiveness

The primary outcome is individual weekly fresh fruit and vegetable purchasing during the 3-6 months post-intervention period. An interaction between intervention group and time period will indicate whether there is a difference in purchasing from the baseline 3 month period to 3-6 month period post-intervention between intervention and control groups.

5.3 Assessment of harms

Risk of harm from this study is low (section 1.1.5). Measuring costs of the intervention to individuals and the retailer, and assessing the diets of participants' young children will enable quality control assessment of unintended negative consequences of the intervention. Research staff will report any adverse events that arise during data collection and these will be routinely monitored during Study Management Committee meetings.

6. OUTCOME MEASURES

6.1 Primary outcome measures

The primary outcome is change in participant's weekly fruit and vegetable purchasing patterns from baseline (3 months prior to refurbishment) to the 3-6 month period post-refurbishment. Change in fruit and vegetable purchasing from baseline to the 0-3 month period post-refurbishment will also be assessed to measure short-term purchasing effects. These data will be obtained through the supermarket chain's loyalty card scheme and provide information about the number of items for each product purchased at each store visit during the study period. During the pilot phase, product categories appropriate for the study were created by the research team from individual product identification data (price look-up (PLU) codes) because the retail categorisation was not appropriate for our research purposes (e.g. fruit and vegetables included potatoes). The same process will be used in the full study. Specific product categories of interest include fresh fruit and vegetables and total spend. We will also examine frozen fruit and frozen vegetables (for

substitution effects). The research team will aggregate these data from each visit to a weekly structure for analysis to enable our data to be presented as per household/per week which is comparable to analyses conducted in previous price reduction supermarket trials.[35, 38]

6.2 Secondary outcome measures

The secondary outcomes include women's and young children's dietary quality, women's daily fruit and vegetable intake, weekly store sales and economic analyses.

6.2.1 Dietary quality

Measures of women's and their young children's dietary quality will be assessed using published tools. 20-item food frequency questionnaires (FFQ) will be used to create standardised diet quality scores for each woman and child.[39, 40] The scores are statistically-derived composite measures that include components to characterise healthy and less healthy dietary habits[41] and can capture changes in patterns of eating that are not obtained through dietary assessment instruments which focus on single food groups.[42] Measures of overall dietary quality have been shown to be important tools in demonstrating dietary inequalities[13, 43] and the relationship between diet and health outcomes such as cardiovascular disease risk.[44] The women's 20-item FFQ was derived from, and correlates highly with, a 100-item FFQ used in the Southampton Women's Survey (SWS, n=6129 women aged 20-34 years).[39] The children's 20-item FFQ was derived from, and correlates highly with, an 80-item FFQ used in the SWS (n=1640 children 3-4 years).[45] The items within the FFQs were selected by identifying the 20 most weighted items in a principal components analysis (10 healthy and 10 less healthy). The same statistically driven process was completed separately to develop an FFQ for women and one for young children. Participants will be asked to indicate how often in the previous month they (or their child) consumed each of the 20 foods. A dietary quality score for each woman or child will be calculated by multiplying their reported frequency of consumption of each of the 20 items from their FFQ by corresponding weightings derived from the appropriate principal components analysis and then summing the results. This process follows recommended methodology.[44] Dietary scores will be standardised to have a mean of 0 and standard deviation of 1. Higher diet scores represent better dietary quality characterised by higher intakes of vegetables, fruit, water and wholegrain bread and lower intakes of white bread, processed meats, chips, crisps and sugar. Dietary quality scores from the children's 20-item FFQ have been shown to correlate highly with a 2-day food diary (r=0.72) in a re-test validation study.[40]

The women's dietary quality score will be validated in this study by asking a random sample of n=150 participants to complete myfood24[46] (a validated online 24hour recall tool) for 3 days (2x weekdays + 1x weekend day). These data will be coded into 100 food groups[41, 43] and a principal components analysis will be used to identify a dietary quality score. For each woman, this score and the dietary score derived from their 20-item FFQ will be compared. A Bland-Altman plot will be used to examine differences, and a correlation coefficient will be calculated. Previous evaluations of diet scores from short FFQs compared to diet diaries have produced correlation coefficients of approximately 0.7.[40, 41] The 95% confidence interval for a correlation coefficient of 0.7 derived from data on n=100 women would range from 0.58 to 0.79.

6.2.2 Daily fruit and vegetable intake

Women's daily fruit and vegetable intake will be measured via a 2-item tool. Examination of the distribution of these data from the pilot identified considerable clumping. In contrast, the dietary quality scores describe above have continuous distributions (mean=0, (SD=1)) and are more sensitive to detect dietary change arising from the intervention. We will assess change in daily portions of fruit and vegetables to quantify the independent effect of this aspect of diet; this measure details change in the amount (quantity) of fruit and vegetables eaten and will provide complementary data to the changes in frequency collected by the FFQ. This 2-item tool has been validated against urinary potassium and plasma ascorbic acid to describe high (≥5 portions/day) and low (≤2.5 portions/day) intake.[47]

6.2.3 Store sales of fruit and vegetables

Store sales data will be provided from electronic transaction records aggregated to the weekly level to enable comparison with previous work.[48] Weekly store sales data will cover 3 months prior to refurbishment

(baseline), and 0-3 and 3-6 months post-refurbishment. Data will cover the same retail weeks for each matched pair of stores to account for seasonal variation. The product categories created for the individual purchasing data will also be created for the store sales data. The specific categories of interest for store-level analyses include fresh fruit and vegetables and total sales, plus frozen fruit and frozen vegetables (for substitution effects).

6.2.4 Economic evaluation

We plan to estimate the costs and effects of the store refurbishment programme over a 10-year time horizon (5 and 30 years in scenario analysis). These long-term projections will require assumptions about the persistence of observed changes to shopping habits and dietary behaviour beyond the 6-month study follow up. We will test a range of possible scenarios, with waning of effects over periods from 6 months to 20 years. The evaluation will be conducted from three perspectives: individual, retailer and societal (full details section 8.3). Individual and retailer results will be presented as simple cost-consequence analysis (CCA) tables, with estimates of monetary costs or savings shown in a 'balance sheet' alongside summary statistics for other relevant outcomes. For the societal perspective, we will conduct a cost-utility analysis (CUA), to assess the efficiency of the investment in store refurbishment in relation to future costs and savings to public and private bodies and health effects for the women, as well as the impact on health inequalities. Health effects and related treatment and care costs will be estimated a Markov model developed for this study. We had intended to use the published $IMPACT_{NCD}$ model for this analysis [49], but this model could not be made to run on the University of Southampton High Performance Computing (HPC) system. We will therefore use a new model, based on similar data sources as the IMPACTNCD model, but with a simplified structure appropriate for the WRAPPED economic analysis. This new model will estimate, the incidence of key health conditions known to be affected by fruit and vegetable consumption (diabetes, , cardiovascular disease, colorectal cancer and breast cancer) for a synthetic population with defined demographic, socio-economic and clinical risk factors.[49] The model structure, assumptions and parameter sources are described in section **Error! Reference source not found.** below. Future costs/savings and Quality Adjusted Life Years (QALYs) will be discounted using rates recommended by the Treasury for appraisal of public programmes and policies: currently 3.5% per year for costs and 1.5% per year for health outcomes (3.5% for both costs and 1.5% for health outcomes in scenario analysis, as recommended for NICE Public Health guidance).[50, 51]

7. STUDY PROCEDURES AND DATA COLLECTION

7.1 Recruitment

Women aged 18 to 60 years, who hold a loyalty card with the collaborating supermarket chain and shopped at least once in a study store in the 12 weeks prior to recruitment will be sent an invitation and information letter. The letter will be sent by the supermarket to comply with data protection laws. The pilot phase demonstrated that between 200 and 300 women per store were contacted using this method and that it was an effective means of recruitment attracting 49% of pilot participants. Interested women will contact the study team via Freephone number, text or email; the majority of pilot participants used text as the initial contact method. They will be screened for eligibility and consented.

In-store recruitment will also be used, whereby members of the research team approach women customers while shopping and provide them with a study information sheet. Women register their interest with the researcher in-store and are phoned at suitable time for them to be consented. This method proved effective at enhancing representation of disadvantaged customers in previous supermarket pricing trials[52] and was used to recruit 34% of pilot participants. Process evaluation interviews with 16 pilot participants identified that they were happy to be approached in these ways. Both intervention and control participants will be recruited using these methods.

Participants are not informed of the intervention. They will be invited to participate in a study that is researching the diet and shopping patterns of women aged 18-60 years and their young children aged 2-6 years.

To boost participant numbers and enhance power for primary outcome (fruit and vegetable purchasing), a final wave of recruitment will be conducted by approaching

i. women aged 18 to 60 years (excluding current study participants or those who previously declined), who hold a loyalty card with the collaborating supermarket chain and shopped at least once in the existing study stores in the 12 weeks prior to recruitment, will be sent an invitation email and text prompts (Appendix 50) from Iceland. Emails will be sent in batches, each containing six stores. Interested women will contact the study team via Freephone number, text or email. Demographic data will be collected from the new participants (Appendix 48). The details of new participants will be sent to Iceland via safesend. Iceland will then email participants asking them to share their retrospective loyalty card data with UoS for a voucher.
ii. Existing participants of the WRAPPED study who have provided demographic and dietary data but not provided Iceland with their consent for their purchasing data for the 9-month study period to be shared with the research team, will be contacted via email and text prompts (Appendix 51) from Iceland to consent for sharing their retrospective loyalty card data for 9 months. Once they provide consent Iceland will be able to share their purchasing data with UoS.

If the response is low to emails in the first batch of six stores, letters in post will be used to contact participants; the content of the email and letter will be the same.

7.2 Consent

Potential participants who register their interest with the study team will be contacted by phone from a study team member to: i) check their eligibility for participation, ii) ensure the participant has received an information letter, iii) confirm the conditions of consent, and iv) book an appointment for the baseline telephone interview when consent will be obtained.

A trained researcher will talk the participant through the consent form and complete the form on the participant's behalf prior to completion of the baseline telephone interview. Participants will be asked:

- to confirm that they have read and understood the information letter,
- if they have any questions about the study,
- to provide verbal consent to take part in the study and have their survey data used for research,
- to provide verbal consent to have their loyalty card sales data for the 9-month period of the study to be shared by the supermarket chain with the study team to be used for research,
- that they understand their participation is voluntary and they can withdraw from the study any time and without reason, and
- to provide verbal consent that they are be happy to be contacted about taking part in future research studies.

To ensure compliance with data protection laws, participants who have consented with the study team and completed the baseline survey will be sent an email from the retailer to seek each participant's explicit consent for the retailer to share the participant's loyalty card data for the study period with the WRAPPED study team. Participants will be required to click the 'I consent' button in the email for their consent to be registered.

Separate consent to take part in qualitative interviews and have the interview voice recorded will be obtained from all those taking in part in the process evaluation qualitative interviews. Invitation letters or emails to take part in an interview will be distributed and those interested will contact the study team. A

researcher will answer any queries, talk the individual through the consent form and sign on their behalf. Consent will also be audio recorded. The anonymity procedure will be made clear and an explanation of how the data will be processed, utilised and stored will be provided. The right to refuse participation or to withdraw from the interviews at any time without giving a reason will be respected.

7.3 Outcome data collection

Women from matched intervention and control stores will be recruited in the same period prior to the intervention stores' refurbishment. Participant weekly purchasing (primary outcome) data will be obtained through the supermarket's loyalty card scheme and will cover the 3 months before refurbishment, plus 0-3 and 3-6 months (primary outcome) post-refurbishment. Information about fresh fruit and vegetable purchases, stores visited, number of visits per week, and total spend per week will be provided by the retailer at the end of the 9 month period for participants from each pair of intervention and control stores. Obtaining participant purchasing information through the loyalty card scheme removes the need to burden participants with the task of collecting and sending supermarket receipts over a 9-month period and the time consuming data entry for the research team.

This study is unique in its collection of individual-level sales data, as well as demographic and dietary information, and is the first supermarket study to collect dietary data for more than one family member.[53] Demographic and dietary data will be collected via telephone survey at baseline (before refurbishment), and 1, 3 and 6 months after refurbishment using a questionnaire that was extensively tested in the pilot study. Baseline and 6 month questionnaires take approximately 30 minutes to complete, while the 1 and 3 month questionnaires take 15 minutes. Using telephone interviews can overcome low-literacy levels and enhance participation of disadvantaged women. Interviewer-administered questionnaires have shown greater accuracy than self-administered questionnaires, particularly for dietary assessment.[54] The process evaluation interviews with pilot participants highlighted that they enjoyed the flexibility to schedule the telephone calls at a location and time convenient for them. Changes in choice that result from nudge interventions need to be assessed at different time points, ideally over several months to determine immediate, intermediate and sustained effects.[55] A systematic review of non-financial supermarket interventions to promote healthy choices, identified that only 7 of the 21 single-component studies had intervention periods lasting at least 2 months and only 4 included follow-up, with none assessing sustained change.[21] The primary outcome time-point for assessing change is 6 months to assess sustained change. Assessment will be made at 3 month because habit formation takes approximately 10 weeks.[56] In the pilot study, the 1 month follow-up proved important for participant engagement. These three follow-up time-points have been applied in previous price reduction supermarket trials.[38]

The questionnaire was tested in the pilot phase and validated measures will be used (see section 6) to collect data on women's dietary quality, daily fruit and vegetable intake and their young children's dietary quality (secondary outcomes). Data about women's demographic characteristics perceptions of their study supermarket's in-store environment, food shopping habits and psychological and social factors will also be collected via telephone interview.

Rolling monthly recruitment of participants and completion of surveys over a 29 month period will minimise bias from seasonal patterns of fruit and vegetable availability or consumption. Bias resulting from new customers shopping at the refurbished intervention stores is omitted through our collection of individual level data. Weekly store sales (secondary outcome) data will be provided from the supermarket's electronic sales data records for the same time periods.

7.4 Participant incentives

The successful recruitment and low attrition rates observed in the pilot phase were likely enhanced by the use of participant incentives in the form of 3x £10 Love2Shop vouchers. Our PPI representatives highlighted that vouchers would be preferable to financial payment among our target audience because of potential interference with benefit payments. PPI representatives also identified that no specific clothing or online

store would be appropriate due to the range in ages and socioeconomic backgrounds of participants. Providing vouchers for the collaborating supermarket would be a conflict of interest but Love2Shop vouchers can be spent in over 20,000 different high street stores. We do not encourage participants to spend the voucher in a particular way. It is common for studies in commercial settings to provide incentives to encourage participation. Our incentive value is similar to an Australian supermarket pricing trial that used incentives of $75AUD to optimise recruitment and retention and produced a comparable retention rate (89%) to our pilot.[35] Distribution follows 1x £10 Love2Shop voucher after completion of baseline, 3 and 6 month questionnaires. During process evaluation interviews, pilot study participants highlighted that these vouchers encouraged them to take-part in the study and continue participating.

For the final wave of recruitment, participants will be offered an incentive of either an Amazon or Love2Shop voucher. In discussion with our PPI representatives, Iceland and study team, we propose to offer £15 incentive in vouchers to any new participants who provides their demographic data and consents with Iceland to provide their loyalty card data to the research team. The voucher will not be dispensed until the participant has given Iceland their consent for their data to be shared. If the response to £15 voucher doesn't generate adequate response, the value of incentive will be increased up to £25.

Existing participants who have provided their demographics and dietary data to the research team have received up to £30 in vouchers for their time to date. We will offer these participants an additional £5 in vouchers to provide consent to Iceland for their purchasing data for the 9-month study period to be shared with the research team. The voucher will not be dispensed until the participant has given Iceland their consent for their data to be shared.

7.5 Process evaluation

A detailed process evaluation will be conducted, following MRC guidance on process evaluation,[57] to assess intervention implementation, mechanisms of impact and context.

7.5.1 Intervention implementation

Intervention fidelity will be assessed in intervention and control stores through regular in-store surveys conducted by trained researchers using published tools that include assessment of product availability, variety and shelf and store position.[14, 58] Details about products placed at the front of the store before and during the intervention will be collected by fieldworkers using a bespoke tool. Store planograms (diagrams indicating product displays) will also provide information about changes in products at the front of the store in both intervention and control stores throughout the study period. Members of the research team will maintain contact with store managers (telephone and store visits) four times over the 9 month period and will be in regular contact with head-office staff.

Intervention exposure will be determined by calculating the number of shopping visits from loyalty card data and will be supplemented by reported frequency of visits to study stores from participant surveys.

Intervention reach will be assessed by combining individual purchasing data with demographic data to identify the characteristics of participants who increased their fruit and vegetable purchases and those who did not.

7.5.2 Mechanisms of intervention impact

Mechanisms of impact will be examined qualitatively through go-along interviews with a purposive subsample of participants (n=30, 15 per arm) and semi-structured interviews with a convenience sample of staff (n=20). Following optimal qualitative research practices, this study will recruit to data saturation.[59] The sample size estimates above are approximations within which we expect saturation to be reached. The go-along interviews will adopt a symbolic interactionist ethnographic approach to examine the interpretations participants assign to physical and social objects during everyday interactions and activities (i.e. food

shopping).[60] Ethnographic investigations of individual food purchasing behaviours in supermarkets are rare.[61] This methodology combines observation and interview[62] and will take the form of an accompanied food-shopping trip in participants' study supermarket. Recruitment to these interviews will be undertaken by purposively inviting equal numbers of those with low (≤GCSE), mid (A-level/HND) and high (degree) educational attainment. Within each of these sub-groups we will seek to recruit women with and without children. A semi-structured interview guide will be developed to be used in a flexible manner as participants will lead and narrate their food choices while shopping. They will be prompted to explain the environmental and social factors that influence their decisions in an effort to understand participants' interactions with the store environment. Observational data about participants' behaviours, purchases made and the store location and environment (including photos with appropriate permissions) will be recorded and used to supplement thematic analysis of the audio-recorded go-along interviews.

Approval from the collaborating supermarket will be sought to conduct staff interviews to offer insight into staff understanding of how placement strategies work to influence customers and the drivers and challenges for retailers in providing more healthful environments to customers. Interviews with participants and staff will explore strategies that have helped women resist supermarket marketing strategies and factors within the food system that facilitate healthier marketing practices among food retailers.

Mechanisms of impact will also be examined quantitatively by using questionnaire data. Potential mediating psychological characteristics including perceived control[63] and nutrition self-efficacy[64] (which may be enhanced due to the removal of physical barriers to accessing fresh produce) will be measured at baseline and 6 month follow-up. Participants' perceptions of their study store environment, including quality and availability of fresh fruit and vegetables, will be measured as part of baseline and 1, 3 and 6 month follow-up surveys to assess any immediate and sustained mediation effects.[65] These pathways have been hypothesised in a widely used food environment conceptual model[66] but rarely tested.

The role of food waste on the relationship between household purchasing and women's dietary quality will be assessed by asking women how frequently they have thrown away fresh fruit and vegetables in the past month. The average UK household loses £470 each year from food waste;[67] 40% comes from produce not being used before spoiling. Food waste may explain any differences in purchasing and dietary outcomes observed in our study.

7.5.3 Intervention context

We will examine how external factors might have influenced intervention delivery or impact. To examine how local context influences participants' food shopping patterns we will collect detailed information about all the supermarkets participants visited in the previous month and conduct audits to assess the in-store environments of those most frequently visited. We plan to complete spatial mapping covering a 2-mile radius around each study store to identify if any competitor supermarkets have opened or closed during the study period.

We will seek to assess the national context via semi-structured interviews with a purposive sample of policy makers (Public Health England, Department of Health and Social Care, Behavioural Insights Team, Department for Environment, Food and Rural Affairs, Scottish Government, Welsh Government), food retail employees and/or representatives (British Retail Consortium, IDG, Aldi, Coop) and researchers and non-government organisations working with food retailers to identify policy, retail business and macroeconomic factors that may have influenced intervention implementation or impact. These interviews will explore the transferability of the intervention, if effective, to other discount and small supermarket chains that do not routinely place fresh produce at the front of their store. We aim to identify policy and business opportunities that may assist in implementing the intervention in other retail outlets.

7.6 Data collection closure

The end of the study data collection period will be considered as the date on which the last participant has completed their 6 month follow-up assessment or when the final qualitative interview has been completed.

8. STATISTICS

8.1 Sample size

Our study has a prospective matched controlled cluster design and the power calculations take account of clustering at the store level, which is essential for the store-based intervention. In a cluster designed study, it is the number of clusters, rather than the number of individuals within each cluster, that are most potent in determining the study's statistical power.[68] Making the cluster a lot larger while keeping the number of clusters fixed yields only a very small increase in power and precision. The need for a large number of stores, rather than a large number of participants, is a key reason why there has been little research in this field.

The study will be powered to detect differences in the primary outcome (fresh fruit and vegetable purchasing) between women in the intervention and control groups during the 3-6 months post-intervention. Average fruit and vegetable purchases per week are not normally distributed, thus sample size calculation is based on changes in average fresh fruit and vegetable purchases per week from the 3 month baseline period to the post-intervention period, which are approximately normally distributed. It was not practical to calculate a rho from the pilot study due to the small number of clusters. We used data from our previous research on women in Hampshire who were the same age-range as the proposed participants of this study[13] and considered the supermarkets at which the women shopped as clusters to estimate a rho of 0.1 as our intraclass correlation coefficient. We aim to detect a difference of 0.3 items (1.5 portions) per week. Assuming a standard deviation of 0.7 items (3.5 portions) per week as seen in the pilot data, 24 stores in each arm and 9 women per store provides 90% power at a 5% significance level (2-sided).

The study will also be powered to assess the secondary outcome of women's dietary quality. This outcome is normally distributed and this sample size calculation is based on the score at 3 month follow-up, adjusted for baseline score. Our previous research provided a rho of 0.1 as our intraclass correlation coefficient and a correlation coefficient of 0.8 for the means of women's dietary quality at the store level between baseline and 2-year follow-up. Taking account of the clustering, and using the method of Teerenstra[69] to adjust for the ANCOVA method of analysis planned (i.e. adjusting diet quality score for baseline in the analyses), 24 stores in each arm with 9 women per store provides 83% power at a 5% significance level (2-sided) to detect a difference in the diet quality scores at follow-up of 0.23 standard deviations (SD).

Assuming that half the women have children aged 2-6 years, as observed in the pilot phase, 24 stores in each arm will also provide 76% power to detect a difference in the children's diet quality scores of 0.25SD using the methods described above. Having fewer participants but retaining the full number of clusters has relatively little impact on the anticipated power.[68]

8.2 Statistical analysis

We will conduct analyses involving 3-level multilevel models, with women's weekly purchasing data clustered within women, who are clustered within stores. Weekly purchasing data are not normally distributed and therefore an alternative continuous distribution such as the negative binomial distribution will be considered. With the data in 'long' format, an interaction between intervention group and time period will indicate whether there is a difference in change in sales from the 3-month baseline period to the 0-3 month and 3-6 month periods post-intervention between the control and intervention stores. These models will be adjusted for sales from the 3-month baseline period as an efficient analysis of the changes in purchasing taking account of regression to the mean.[70] We will also adjust for confounders of the relationship between store group and purchasing as determined using a Directed Acyclic Graph.[71] The pilot data revealed that a small number of intervention participants visited stores that were not in the study (no control participants visited an intervention store); intention-to-treat analysis will therefore be used where

women are analysed according to the group they were originally assigned at baseline. Since data from matched intervention and control stores will be collected over the same time periods we do not anticipate that seasonality will be a confounder. If there is evidence of bias due to seasonal differences between intervention and control data collection we will adjust for this in the analysis.

Effect modification by educational level will be assessed by including a multiplicative interaction between intervention group and education level in the individual purchasing models. If there is evidence of an interaction, stratified analyses will be performed to determine the strength and direction of intervention effects for each level of educational attainment. We will also test for interaction by age at baseline (18-45 years, 46-60 years).

Women's dietary quality scores (SD) will be calculated at baseline, 3 and 6 months, with the score the outcome measure and intervention group the exposure. Due to sparse data (small numbers of women per store) the first three-level (women clustered within stores within pairs) multilevel model did not fit. Therefore, before further multilevel models were attempted, a decision was taken to run a linear regression model in each pair of stores and combine the results using meta-analysis. Previous research (by Georgia Ntani at the MRC LEC) suggests that this meta-analysis approach usually produces equivalent results to multilevel models. Baseline diet scores will be included in the model to account for regression to the mean.[70] Confounders will be determined by a Directed Acyclic Graph. Analyses of other secondary outcomes (i.e. daily fruit and vegetable intake and child's dietary quality) will adopt the same statistical approach as that for women's dietary quality.

Store sales data in a variety of categories, including total sales, fresh fruit and vegetable, and frozen fruit and vegetables will be analysed using multilevel models to adjust for the clustering of weeks within stores. Weekly sales data will be the outcome and will be analysed using Interrupted Time Series models.[72] Statistical analyses will be conducted in Stata.[73]

8.3 Economic analyses

8.3.1 Individual perspective

The outcomes of interest for the CCA balance sheet will be costs and benefits of the intervention that have a direct impact on shopping choices and welfare, including: net impact on household expenditure (spend on food and related time and travel costs); satisfaction with shopping environment; indicators of diet quality for women and children; and projected health effects for the women (e.g. 10-year probability of a cardiovascular event from model). Individual loyalty card data will be used to provide information on the number of store visits and change in total spend and fruit and vegetable purchases. This will be supplemented by data from participant surveys on total monthly spend on household foods to estimate potential displacement of expenditure from other stores, total time spent food shopping in the past month to capture overall time costs, as well as the name and location of supermarkets used in the previous month and frequency of visits to each store to calculate total distance travelled. For equity reasons, time costs will be calculated using a fixed national median hourly wage (net of tax) to avoid placing a different value on individuals' time based on their level of economic activity or income. Travel costs will be calculated using a fixed travel cost per mile.

8.3.2 Retailer perspective

These analyses will assess factors likely to influence supermarket decisions about investments in food product and placement strategies similar to the intervention in this study. The CCA balance sheet will include an estimate of the net financial impact of the programme of store refurbishments, alongside indicators of satisfaction from the participant survey. Costs will be estimated by discussion with supermarket staff may include: cost and expected lifespan of previous store refurbishment (including capital costs and costs of store closure days for refurbishment), the costs and expected lifespan of current store refurbishment (fresh fruit and vegetable store entrance), ongoing costs such as additional refrigerator storage, extra produce deliveries (transport costs), produce waste costs, changes in product group sales (displacement,

substitutions and complements) and staff costs at head office and store level. Results will be presented at an aggregated level to respect commercial confidentiality. The financial impact of changes in sales volumes will be estimated using publicly available information to reflect expected profit margins within the industry.

8.3.3 Societal perspective

Costs will be estimated for resources associated with the capital investment and ongoing costs of the store refurbishment, changes in food expenditure, time and travel costs for individuals and health and social care costs for related health conditions. This analysis is designed to inform decision-making by local authorities and other public bodies about the value of encouraging initiatives to improve the placement of fruit and vegetables in food retailers. The sources of data for quantifying resource use associated with the intervention are similar as for the individual and retailer perspectives, but the principles of costing are rather different. For example, the value of individual' time will be costed using a gross hourly wage rate, including tax.

We had intended to use the IMPACT$_{NCD}$ model to predict how changes in women's diet quality will affect health outcomes and related treatment and care costs.[49] However, this model could not be made to run on the University of Southampton's High Performance Computing system. We will therefore use a new Markov model for WRAPPED, programmed in Microsoft Excel.

The WRAPPED economic model will estimate the impact of a change in fruit and vegetable consumption on the incidence of type 2 diabetes, cardiovascular disease, colorectal cancer and breast cancer, as well as death from other causes.[74-76] Each of the four diseases of interest is associated with an impact on health-related quality of life (HRQoL), mortality and excess health and social care costs. Individual-level data from the Health Survey for England 2016 and the Qrisk3, Qdiabetes and Qcancer risk equations will be used to characterise baseline fruit and vegetable consumption and incidence risks for the four diseases, stratified by age (in decades from 20-30 years to 80-90 years) and deprivation (Index of multiple deprivation quintiles).[77-80] Other cause mortality will be based on general population lifetables with excess mortality related to cardiovascular disease, breast cancer and colorectal cancer removed, and with adjustment for age and deprivation strata.[81-87] HRQoL (utility) will be based on general population estimates from the Health Survey for England adjusted for age and deprivation, with disutilities for the four disease health states from the literature.[88, 89] Health and social care costs associated with the four diseases will also be taken from the literature.[90-93] Outcomes for the intervention arm will be modelled using a mean difference in fruit and vegetable portions per day, estimated from the purchasing data, and relative risks for the incidence of the four diseases and mortality per unit increase in fruit and vegetable consumption from the literature.[94]

Results of the societal CUA will be presented as an incremental cost per QALY gained, unless the store refurbishment intervention is dominant (lower costs and more QALYs) or dominated (higher costs and fewer QALYs) compared with the control.

Uncertainty over the results will be explored in sensitivity analysis. Deterministic sensitivity analysis will be used to test the impact of input parameters and key structural uncertainties, including the time horizon, waning of effect on diet quality and discount rates. Probabilistic sensitivity analysis will be used to reflect collective uncertainty over the distribution of input parameters. This will be used to produce ranges around key outputs, including medians and interquartile ranges for estimates of the number of CVD cases prevented, CVD deaths, QALYs and costs.

8.4 Qualitative data analyses

Audio-recordings of all process evaluation interviews will be transcribed verbatim. For the go-along interviews, the transcripts will include references to field notes and any photos taken during the interviews to enable coding and analysis of both verbal and non-verbal behaviours. QSR Nvivo Software 11 will be used to organise and analyse transcribed data. Separate coding frameworks for participants, supermarket staff and policy makers/food retail representatives will be developed based on themes arising using inductive

coding. Using a constant comparative method, the frameworks will be refined via double-coding of transcripts and meetings to discuss the usefulness and validity of themes and sub-themes and the compilation of verbatim quotations. Where appropriate and useful, thematic maps will be produced to graphically represent the qualitative findings.[95]

9. GOVERNANCE AND STUDY MANAGEMENT

9.1 Sponsor

The sponsor for this study is the University of Southampton.

9.2 Funding

Funding for this project has been received from the National Institute for Health Research (NIHR) Public Health Research Programme, NIHR Southampton Biomedical Research Centre and Medical Research Centre.

9.3 Study management

The PI will chair Study Management meetings with study members, held monthly, to track progress and budget plans. Standard operating procedures have been developed to ensure quality assurance with data collection and adherence to the study protocol. Meetings will be held with co-applicants and collaborators to provide their expertise as needed.

The PI will develop progress reports and a final report at the conclusion of the study. Publications for peer-reviewed scientific journals will also be produced.

9.4 Data monitoring and quality assurance

The Study Steering Committee will be independent, with an experienced independent chair and will include PPI members. Representatives from charities working with food retailers will be approached to join. The Committee will meet biannually. The Committee will provide strategic guidance and monitor progress and professional conduct. Terms of reference for the SSC will be developed, drawing on standard guidelines but acknowledging specific features of this study.[96]

There will no Data Monitoring Committee as risks to participants are low.

9.5 Insurance and indemnity

The UK sponsor of the project is the University of Southampton. The sponsor has no-fault compensation and legal liability insurance, giving indemnity cover for non-negligence and alongside all claims against the investigators.

10. ETHICAL ARRANGEMENTS

10.1 Ethical approval

Ethical approval for the WRAPPED study and the participant incentive has been obtained from the University of Southampton, Faculty of Medicine Ethics Committee (ID 20986.A4). NHS Research Ethics Committee approval for the study is not necessary, nor even permissible as the participants are not recruited through the NHS. Should a protocol amendment be made that requires ethics committee approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant and information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the ethics committee. Details of the consent procedures are given in section 7.2.

This study will be conducted in accordance with the Declaration of Helsinki, Good Clinical Practice guidance, Research Governance Framework for Health and Social Care and Data Protection regulations.

Risks to participants and researchers involved in this study are low. The intervention is health-promoting and has potential benefits for the participants and their families. Distress to participants and supermarket staff is unlikely due to the use of validated measures in study questionnaires and the reflective nature of the qualitative methods that will be used. All participants will be reminded that there are no 'correct' answers and of their right to withdraw from the study at any point without reason. Outward facing materials will be co-designed with PPI representatives to ensure they are appropriate for participants.

10.2 Statement of confidentiality

The PIs, research team and data management team will preserve the anonymity and confidentiality of participants in accordance with MRC LEU and University of Southampton protocols and Data Protection regulations. A system of linked anonymity will be created for this study whereby identification (ID) numbers are allocated to each participant and all personal details will be kept separate from survey results including questionnaires and purchasing data. For the purposes of this project, only ID numbers will be used, as the research question is looking for population change. It will not be necessary to identify any of the participants in order to answer the research questions.

For the qualitative interviews, confidentiality and unlinked anonymity will be assured. Information will not be reported in a way, which would allow an individual participant to be identified. The research team will only have access to the name and signature of participants as recorded on the consent form and this will not be linked to the responses received from an individual during a conversation.

11. DATA HANDLING, SHARING AND STORAGE

Data collection procedures will be conducted in accordance with standardised protocols, and, as necessary, quality assessments such as inter-observer variability studies and interval re-training will be completed. Survey data will be double-entered into separate Microsoft Access databases. These entries will then be compared to ensure the accuracy of the data entry. In-house programmes will be developed to highlight out of range values or inconsistencies in the data.

Data security risks in this study are limited, however, could include i) access and misuse by unauthorised personnel and ii) damage or loss through fire etc. Data handling, sharing and storage procedures will be conducted in accordance with a study data management plan and data protection regulations. Data access will be strictly controlled by the PI, co-PI and MRC LEU Data Manager. All data will be stored on password protected secure systems, including encrypted laptops/servers, on an ongoing basis and completed paper-based data documents will be stored in locked filing cabinets in secure buildings. All essential data will be retained for up to 10 years following the end of the study and destroyed using standard University of Southampton and MRC LEU procedures at the end of the statutory period.

Due to the personal and commercial sensitives of data collected during this project, datasets will not be publically available but may be made available upon request, subject to appropriate confidentiality and licensing approvals and in accordance with MRC LEU and University of Southampton policies. Food purchasing and sales data are confidential and cannot be shared due to the conditions of the agreement with the collaborating retailer. Transfer of data between study team members and collaborators will take place in accordance with signed agreements and through secure servers using encryption software or personal transfer through trusted personnel.

Backups of all data will carried out daily and copies transferred to an off-site location in accordance with the MRC LEU backup policy. The MRC LEU data manager and the study team will keep single master files of all data, maintain a log of changes to data, and archive old versions.

12. PUBLICATION PROCEDURE

The publication procedure will respect the rights of all contributors to be adequately represented in outputs (e.g. authorship and acknowledgments) and the study to be appropriately acknowledged. The authorship will be in line with the international guidelines (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html). Participants will not be identified in any publications. Publishing approvals outlined in signed agreements relating to this study will be adhered to.

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