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**Protocol of a natural experiment to evaluate a discount supermarket intervention to improve food purchasing and dietary behaviours of women (WRAPPED study): a prospective matched-controlled cluster design**

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-036758
Article Type:	Protocol
Date Submitted by the Author:	01-Jan-2020
Complete List of Authors:	Vogel, Christina; University of Southampton, MRC Lifecourse Epidemiology Unit Crozier, S; University of Southampton and Southampton University Hospitals NHS Trust, Institute of Developmental Sciences Dhuria, Preeti ; University of Southampton, MRC Lifecourse Epidemiology Unit Shand, Calum; University of Southampton, MRC Lifecourse Epidemiology Unit Lawrence, Wendy; University of Southampton, MRC Lifecourse Epidemiology Unit Cade, Janet; University of Leeds, School of Food Science and Nutrition Moon, Graham; University of Southampton, Geography and Environment Lord, Joanne; University of Southampton, Southampton Health Technology Assessments Centre Ball, Kylie; Deakin University, Centre for Physical Activity and Nutrition Research Cooper, Cyrus; University of Southampton and Southampton University Hospitals NHS Trust, MRC Lifecourse Epidemiology Unit Baird, Janis; University of Southampton, MRC Epidemiology Resource Centre
Keywords:	NUTRITION & DIETETICS, PUBLIC HEALTH, PREVENTIVE MEDICINE, HEALTH ECONOMICS

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3 **Protocol of a natural experiment to evaluate a discount supermarket intervention to**  
4 **improve food purchasing and dietary behaviours of women (WRAPPED study): a**  
5 **prospective matched-controlled cluster design**  
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10 Christina Vogel<sup>1 2</sup>, Sarah Crozier<sup>1</sup>, Preeti Dhuria<sup>1</sup>, Calum Shand<sup>1</sup>, Wendy Lawrence<sup>1 2</sup>,  
11 Janet Cade<sup>6</sup>, Graham Moon<sup>4</sup>, Joanne Lord<sup>3</sup>, Kylie Ball<sup>5</sup>, Cyrus Cooper<sup>1 2</sup>, Janis Baird<sup>1 2</sup>  
12  
13  
14  
15

- 16 1. Medical Research Council Lifecourse Epidemiology Unit, University of  
17 Southampton, Southampton General Hospital, Tremona Road, Southampton SO16  
18 6YD United Kingdom  
19  
20 2. National Institute for Health Research Southampton Biomedical Research Centre,  
21 University of Southampton and University Hospital Southampton NHS Foundation  
22 Trust, Tremona Road, Southampton SO16 6YD United Kingdom  
23  
24 3. Southampton Health Technology Assessments Centre, Wessex Institute, University  
25 of Southampton, Alpha House, Enterprise Road, Southampton Science Park,  
26 Southampton, SO16 7NS United Kingdom  
27  
28 4. Geography and Environmental Science, University of Southampton, University  
29 Road, Southampton, SO17 1BJ United Kingdom  
30  
31 5. Institute of Physical Activity and Nutrition Research, Institute of Physical Activity  
32 and Nutrition Research, School of Exercise and Nutrition Sciences, Deakin  
33 University, 75 Pigdons Road, Geelong, Victoria 32165 Australia  
34  
35 6. School of Food Science and Nutrition, University of Leeds, Leeds LS2 9JT United  
36 Kingdom  
37

38  
39 **Correspondence to:** Christina Vogel, cv@mrc.soton.ac.uk, Tel: 023 8076 4042,  
40 University of Southampton, Southampton General Hospital, Tremona Road,  
41 Southampton SO16 6YD, UK  
42

43 **Word count:** 3993/4000  
44  
45  
46

47 **Key words:** Dietary behaviour, supermarkets, food purchasing, natural experiment, product  
48 placement, women  
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2  
3 1 **Abstract** (300/300 words)  
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5  
6 2 *Introduction:* Poor diet is a leading risk factor for non-communicable diseases and costs the  
7  
8 3 NHS £5.8 billion annually. Product placement strategies used extensively in food outlets, like  
9  
10 4 supermarkets, can influence customers' preferences. Policy makers, including the UK  
11  
12 5 Government, are considering legislation to ensure placement strategies promote healthier  
13  
14 6 food purchasing and dietary habits. High-quality scientific evidence is needed to inform  
15  
16 7 future policy action. This study will assess whether healthier placement strategies in  
17  
18 8 supermarkets improve household purchasing patterns and the diets of more than one  
19  
20 9 household member.  
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23  
24 10 *Methods and Analyses:* This natural experiment, with a prospective matched controlled  
25  
26 11 cluster design, is set in discount supermarkets across England. The primary objective is to  
27  
28 12 investigate whether enhanced placement of fresh fruit and vegetables improves household-  
29  
30 13 level purchasing of these products after six months. Secondary objectives will examine: i)  
31  
32 14 differences in intervention effects on purchasing by level of educational attainment, ii)  
33  
34 15 intervention effects on the dietary quality of women and their young children, iii)  
35  
36 16 intervention effects on store-level sales of fruit and vegetables, and iv) cost-effectiveness of  
37  
38 17 the intervention from individual, retailer and societal perspectives. Up to 810 intervention  
39  
40 18 and 810 control participants will be recruited from 18 intervention and 18 matched control  
41  
42 19 stores. Eligible participants will be women aged 18-45 years, who hold a loyalty card and  
43  
44 20 shop in a study store. Each control store will be matched to an intervention store on: i) sales  
45  
46 21 profile, ii) neighbourhood deprivation and iii) customer profile. A detailed process evaluation  
47  
48 22 will assess intervention implementation, mechanisms of impact and, social and  
49  
50 23 environmental contexts.  
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56 24 *Ethics and Dissemination:* Ethical approval was obtained from the University of  
57  
58 25 Southampton, Faculty of Medicine Ethics Committee (ID 20986.A5). Primary, secondary and  
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3 26 process evaluation results will be submitted for publication in peer-reviewed scientific  
4  
5 27 journals and shared with policy makers.  
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8 28 *Registration:* ClinicalTrials.gov registration: NCT03573973  
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15 31 *Strengths and limitations of this study*  
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- This study is unique; unlike current literature, it will provide evidence of product placement intervention effects from a cluster trial with adequate statistical power.
  - The outcomes of this study include household purchasing data from loyalty card use over a nine-month period, as well as dietary quality derived from food frequency questionnaires administered at four different time points.
  - This is the first supermarket placement study to provide dietary quality outcome data from more than one household member.
  - Randomisation of stores was not possible within this commercial setting, however, the criteria used to match stores increases the similarity of intervention and control stores and reduces effects of confounding.
  - This study tests a single component intervention; this is scientifically advantageous because it enables assessment of the isolated effects of this particular placement intervention, which improves the availability of fresh fruit and vegetables and positions them in the prominent front-of-store location.

## 1 Introduction

Poor diet is a leading risk factor for obesity and non-communicable diseases (NCDs).<sup>1</sup> In the UK, the cost of poor diet-related ill health to the NHS is £5.8 billion annually, and as many as 42,000 deaths could be prevented each year if people ate more fruit and vegetables.<sup>2</sup>

Inadequate intake of fruit and vegetables is of particular concern among low-income groups.<sup>3</sup>

Women represent an important target group for improving the diets of the broader population; they remain household food gatekeepers, dominating decisions about food shopping,<sup>4</sup> plus the short and long-term health of children is influenced by their mothers' food choices.<sup>5</sup> The Scientific Advisory Committee on Nutrition has expressed concern over the poor diets of young women in the UK and the impact on their children.<sup>6</sup> Improving the nutritional status of women before, during and after pregnancy is important for obesity prevention and is a priority in UK policy (Healthy Lives Healthy People; The Health of the 51%: Women).<sup>7 8</sup> Identifying strategies that support women of childbearing age, particularly those from disadvantaged backgrounds, to make healthy food choices could improve public health now and in the future.

Systematic reviews have shown that interventions providing information about healthy dietary behaviours alone are largely ineffective among disadvantaged groups and that campaigns such as '5-a-day' may even increase inequalities.<sup>9 10</sup> Evidence for interventions that are effective among disadvantaged populations remains limited, however, those addressing the broader environmental determinants of diet appear most promising.<sup>11</sup> It has been purported that information campaigns may be amplifying inequalities because they require high psychological agency, or conscious awareness of behavioural habits, which tends to be lower among disadvantaged groups.<sup>12</sup> In contrast, alterations to environmental stimuli can evoke unconscious reactions or improvements in health behaviours.<sup>13</sup> UK

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3 61 observational research supports this notion and suggests that unhealthy food environments  
4  
5 62 may be exacerbating dietary inequalities. In Cambridgeshire, associations between exposure  
6  
7 63 to fast food outlets and fast food intake were most pronounced among adults of low  
8  
9 64 socioeconomic status.<sup>14</sup> In Hampshire, shopping at less healthy supermarkets, with poorer  
10  
11 65 availability, pricing and placement of healthy foods, was associated with poor dietary quality  
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13 66 among women who left school aged 16 years but not among those with degree  
14  
15 67 qualifications.<sup>15</sup>

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20 68 Almost 90% of UK grocery sales occur within supermarkets<sup>16</sup> and the subtle use of  
21  
22 69 marketing techniques influences the food choices of an almost captive market. A recent  
23  
24 70 survey suggests that two-thirds of all placement marketing strategies used to promote food  
25  
26 71 and beverages in UK supermarkets were for unhealthy products.<sup>17</sup> Additionally, discount and  
27  
28 72 small supermarkets have been shown to have less healthy in-store environments than other  
29  
30 73 supermarkets, including poorer placement of fresh fruit and vegetables.<sup>18</sup> This is concerning  
31  
32 74 because these types of stores are used more regularly by disadvantaged families and younger  
33  
34 75 adults who have poorer dietary behaviours.<sup>19 20</sup> The UK Government are considering banning  
35  
36 76 the prominent placement of unhealthy foods in outlets like supermarkets.<sup>21</sup> Evaluating  
37  
38 77 strategies in discount or small supermarkets that aim to improve the placement of fruit and  
39  
40 78 vegetables could expand the government's intended policy and would aid understanding of  
41  
42 79 their effects among a population with the most to gain from dietary improvements.

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49 80 Systematic reviews of supermarket interventions targeting the in-store environment, such as  
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51 81 product placement strategies that alter the availability and positioning of healthy or unhealthy  
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53 82 foods, show promising effects.<sup>22-24</sup> The majority of studies, however, have poor  
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55 83 methodological quality. Many have not included a control group nor reported sample size  
56  
57 84 calculations, and none included an adequate number of stores for a cluster design study.  
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3 85 Additionally, very few studies assessed the effect of product placement changes on outcomes  
4  
5 86 at the individual level (i.e. customers' purchasing and dietary patterns), with most assessing  
6  
7 87 change at the store level.<sup>24</sup> Not a single study reported on cost-effectiveness.<sup>23</sup> Further high  
8  
9 88 quality, adequately powered studies are needed to quantify the effect of placement  
10  
11 89 interventions in supermarkets. Studies that measure cost-effectiveness and examine  
12  
13 90 differential effects by socioeconomic status are particularly important for policy makers. The  
14  
15 91 collaboration with a discount supermarket chain established for this study provides a unique  
16  
17 92 opportunity to evaluate, on a large scale, the effectiveness and cost-effectiveness of creating a  
18  
19 93 healthier store layout in supermarkets frequently used by disadvantaged families.  
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## 25 94 *1.1 Study objectives*

### 26 27 28 95 1.1.1 Primary Objective:

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30  
31 96 To assess whether increasing availability of fresh fruit and vegetables and positioning them at  
32  
33 97 the front of the store in discount supermarkets improves fresh fruit and vegetable purchasing  
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35 98 patterns 6 months after intervention commencement amongst women customers aged 18-45  
36  
37 99 compared to control customers.  
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### 41 42 100 1.1.2 Secondary Objectives:

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44  
45 101 i. To assess effect modification by educational attainment on women's change in fruit  
46  
47 102 and vegetable purchasing.  
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50 103 ii. To assess how the intervention affects women's dietary quality and daily fruit and  
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52 104 vegetable intake, and the dietary quality of their young children.  
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55 105 iii. To assess how the intervention influences weekly store sales of fruit and vegetables.  
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57  
58 106 iv. To conduct an economic evaluation from individual, retailer and societal perspectives.  
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3 107 v. To conduct a detailed process evaluation to examine: i) intervention implementation  
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5 108 in each store and the exposure and reach to participants, ii) mechanisms of  
6  
7 109 intervention impact by exploring the experiences of participants and staff, and iii)  
8  
9 110 how contextual factors, such as social influences, spatial access to supermarkets and  
10  
11 111 government policy, influence intervention effects.  
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## 15 112 **2 Methods and Analyses**

### 16 113 *2.1 Study Design*

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19 114 The WRAPPED (Women's Responses to Adjusted Product Placement and its Effects on  
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21 115 Diet) study is a natural experiment with prospective matched controlled cluster design. It has  
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23 116 a 6-month intervention period and baseline, 0-3 month post and 3-6 month follow-up  
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25 117 assessments of intervention effects (see flow-chart, Figure 1).  
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### 32 118 *2.2 Study Setting*

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34  
35 119 WRAPPED focuses on women from disadvantaged backgrounds and will therefore sample  
36  
37 120 from customer who shop at stores of the collaborating discount supermarket chain situated in  
38  
39 121 more socioeconomically deprived neighbourhoods across England. The collaborating  
40  
41 122 supermarket has over 900 stores nationwide and holds approximately 2% of the grocery  
42  
43 123 market share in the UK.<sup>25</sup>  
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48 124 This study will sample 36 stores, 18 intervention and 18 control stores; allocation to  
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50 125 intervention condition will be at the store level. Intervention stores will be selected, in a  
51  
52 126 phased approach, from the collaborating supermarket's ongoing refurbishment programme.  
53  
54 127 Randomised controlled trial methodology in real-world supermarket research is limited  
55  
56 128 because it requires commitment that is problematic in this highly competitive, commercial  
57  
58 129 setting. In WRAPPED, randomisation of stores is also not viable within the company's  
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3 130 business model. Consequently, control stores will be matched to an intervention store based  
4  
5 131 on: i) sales profile, ii) customer profile, and iii) neighbourhood deprivation (Index of Multiple  
6  
7 132 Deprivation).<sup>26</sup> Matching on these factors increases the similarity of intervention and control  
8  
9 133 stores and reduces effects of confounding. We will seek to select control stores located at  
10  
11 134 least 20 miles from an intervention store to reduce contamination effects of control women  
12  
13  
14  
15 135 shopping at intervention stores.

### 18 136 2.3 *Intervention and control conditions*

19  
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21  
22 137 The WRAPPED intervention incorporates both placement interventions from the typology of  
23  
24 138 interventions in proximal physical micro-environments (TIPPME): availability and  
25  
26 139 position.<sup>27</sup> The intervention creates a healthier store layout by expanding the produce section  
27  
28 140 to increase the availability of fresh fruit and vegetables, and positioning the section towards  
29  
30 141 the front of the store. The supermarket chain will implement the intervention and will cover  
31  
32 142 new display infrastructure and staff training costs (quality management etc). The intervention  
33  
34 143 will be implemented throughout the year, excluding the Christmas retail period, phased  
35  
36 144 across 22 months and commencing in 2019. The logic model (Figure 2) specifies the  
37  
38 145 intervention components and the route of impact for the short-, medium- and long-term. The  
39  
40 146 model specifies that disadvantaged women will be exposed to the in-store product placement  
41  
42 147 changes which will increase their purchasing of fresh fruit and vegetables (short-term  
43  
44 148 outcome) that in turn will improve their own and their young children's dietary quality  
45  
46 149 (medium-term outcomes) and subsequently reduce inequalities in diet and obesity (long-term  
47  
48 150 outcomes). This study will assess the short- and medium-term outcomes.  
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54  
55 151 The control condition is the previous layout of stores with a limited range of fresh fruit and  
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57 152 vegetables, placed at the back of the store. Both control and intervention stores will be  
58  
59 153 sampled from locations across England to improve generalisability.  
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3 154 *2.4 Eligibility criteria*  
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6 155 Participants will be women, aged 18-45 years, who hold a loyalty card with the study  
7  
8 156 supermarket chain and have shopped in a study store in the 12-weeks before recruitment  
9  
10 157 (according to loyalty card data). Shoppers who choose items in-store but opt for home  
11  
12 158 delivery will be eligible. Women under the age of 18 or over 45 years, who do not hold a  
13  
14 159 loyalty card or only shop online will not be eligible to participate.  
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19 160 *2.5 Participant recruitment*  
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22 161 Women from matched intervention and control stores will be recruited in the same period  
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24 162 prior to the intervention implementation stores' refurbishment. Rolling recruitment over  
25  
26 163 approximately two years will minimise bias from seasonal patterns of fruit and vegetable  
27  
28 164 availability or consumption. Eligible women, identified from the loyalty card register, will be  
29  
30 165 sent an invitation and information letter. Participants are not informed of the intervention.  
31  
32 166 The letter invites them to participate in a study that is researching the food shopping and  
33  
34 167 eating patterns of women aged 18-45 years. The letter will be sent by the supermarket to  
35  
36 168 comply with data protection laws. Interested women will contact the study team via  
37  
38 169 Freephone number, text or email; they will be screened for eligibility and consented. In-store  
39  
40 170 recruitment will also be used, whereby members of the research team approach women  
41  
42 171 customers while shopping and provide them with a study information sheet. Women will  
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44 172 register their interest with the researcher in-store and are phoned at a suitable time for them to  
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46 173 be consented. This method proved effective at enhancing representation of disadvantaged  
47  
48 174 customers in a previous supermarket pricing trial.<sup>28</sup> Both intervention and control participants  
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50 175 will be recruited using these two methods which were identified as most successful during  
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52 176 feasibility testing.  
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3 177 To ensure compliance with data protection laws, participants who have provided informed  
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5 178 consent to the study team and completed the baseline survey will be sent an email from the  
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8 179 collaborating supermarket to seek explicit consent for their loyalty card data, covering the 9-  
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10 180 month study period, to be shared with the WRAPPED study team. Separate consent to take  
11  
12 181 part in the process evaluation sub-studies will be obtained. Participants can withdraw from  
13  
14 182 the study at any point without giving a reason and without affecting their relationship with  
15  
16 183 the collaborating supermarket.

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20 184 All participants will be offered up to £30 Love2Shop vouchers as compensation for their time  
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22 185 given to the study. Our Patient and Public Involvement (PPI) representatives highlighted that  
23  
24 186 vouchers would be preferable to financial payment which may interfere with benefit  
25  
26 187 payments. Our incentive value is similar to an Australian supermarket pricing trial that used  
27  
28 188 incentives equivalent to \$75AUD to optimise recruitment and retention.<sup>29</sup> Distribution will  
29  
30 189 entail 1x £10 Love2Shop voucher after completion of baseline, 3 and 6 month questionnaires.  
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## 34 35 190 *2.6 Outcome measures*

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37  
38 191 This study is unique in its collection of individual-level sales data, as well as demographic  
39  
40 192 and dietary information, and is the first supermarket study to collect dietary data for more  
41  
42 193 than one family member.<sup>30</sup> Primary (purchasing) and secondary (store sales) outcome data  
43  
44 194 will be obtained through the supermarket's loyalty card scheme; other secondary outcome  
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46 195 (dietary quality, fruit and vegetable intake) and demographic data will be collected via  
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48 196 telephone surveys at baseline and 1, 3 and 6 months after intervention commencement. Using  
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50 197 telephone interviews can overcome low-literacy levels and enhance participation of  
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52 198 disadvantaged women.  
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3 199 2.6.1 Primary outcome  
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6 200 The primary outcome is change in participant's weekly fruit and vegetable purchasing  
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8 201 patterns from baseline (3 months prior to refurbishment) to the 3-6 month period post-  
9  
10 202 refurbishment. Change in fruit and vegetable purchasing from baseline to the 0-3 month  
11  
12 203 period post-refurbishment will also be assessed to measure short-term purchasing effects.  
13  
14 204 These data will be obtained through the supermarket chain's loyalty card scheme and provide  
15  
16 205 information about the number of items for each product purchased at each store visit during  
17  
18 206 the study period. We will also examine sales of frozen fruit and vegetables (for substitution  
19  
20 207 effects). The research team will aggregate these data from each visit to a weekly structure for  
21  
22 208 analysis to enable our data to be presented as items (bags of fruit/vegetables because these  
23  
24 209 products are not sold singly at the collaborating supermarket chain) per household per week  
25  
26 210 which is comparable to analyses conducted in previous supermarket trials.<sup>29 31</sup>  
27  
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32 211 2.6.2 Secondary Outcomes  
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36 212 The secondary outcomes include women's and young children's dietary quality, women's  
37  
38 213 daily fruit and vegetable intake, weekly store sales and economic analyses. Measures of  
39  
40 214 women's and their young children's **dietary quality** will be assessed using published tools.<sup>32</sup>  
41  
42 215 <sup>33</sup> Participants will be asked to indicate how often in the previous month they (or their child)  
43  
44 216 consumed each of the 20 foods. A dietary quality score for each woman or child will be  
45  
46 217 calculated by multiplying their reported frequency of consumption of each of the 20 items  
47  
48 218 from their food frequency questionnaire (FFQ) by corresponding weightings derived from the  
49  
50 219 appropriate principal components analysis and then summing the results. Dietary scores will  
51  
52 220 be standardised to have a mean of 0 and standard deviation of 1. Higher diet scores represent  
53  
54 221 better dietary quality characterised by higher intakes of vegetables, fruit, water and  
55  
56 222 wholegrain bread and lower intakes of white bread, processed meats, fried/oven chips, crisps  
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3 223 and sugar. Women's daily **fruit and vegetable intake** will be measured via a 2-item tool.<sup>34</sup>  
4  
5 224 We will assess change in daily portions of fruit and vegetables to quantify the independent  
6  
7 225 effect of this aspect of diet; this measure details change in the amount (quantity) of fruit and  
8  
9 226 vegetables eaten and will provide complementary data to the changes in frequency collected  
10  
11 227 by the FFQ. **Store sales data** will be provided from electronic transaction records aggregated  
12  
13 228 to the weekly level to enable comparison with previous work.<sup>35</sup> Weekly store sales data will  
14  
15 229 cover the periods from 3 months prior to refurbishment (baseline), and 0-3 and 3-6 months  
16  
17 230 post-refurbishment. Data will cover the same retail weeks for each matched pair of stores to  
18  
19 231 account for seasonal variation. The product categories created for the individual purchasing  
20  
21 232 data will also be used for the store sales data.

### 22 233 2.6.3 Economic evaluation

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29 234 The economic evaluation will be conducted from three perspectives, individual, retailer and  
30  
31 235 societal, and plans to estimate the costs and effects of the store refurbishment programme  
32  
33 236 over 5, 10 and 20-year time horizons using scenario analyses. These long-term projections  
34  
35 237 will require assumptions about the persistence of observed changes to shopping habits and  
36  
37 238 dietary behaviour beyond the 6-month study follow up. A range of possible scenarios will be  
38  
39 239 assessed, with waning of effects over periods from 6 months to 20 years. Individual and  
40  
41 240 retailer results will be presented as simple cost-consequence analysis (CCA) tables, with  
42  
43 241 estimates of monetary costs or savings shown in a 'balance sheet' alongside summary  
44  
45 242 statistics for other relevant outcomes. **Individual perspective** evaluation will use participant  
46  
47 243 survey data for food expenditure, time spent food shopping, fruit and vegetable waste as well  
48  
49 244 as travel costs to and from supermarkets; these data will be supplemented by loyalty card  
50  
51 245 data. **Retailer perspective** estimates will be generated through discussion with supermarket  
52  
53 246 staff. These may include the cost and expected lifespan of the intervention, ongoing costs  
54  
55 247 such as additional refrigerator storage, extra produce deliveries, produce waste, changes in  
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3 248 product group sales (displacement, substitutions and complements) and staff costs. Results  
4  
5 249 will be presented at an aggregated level to respect commercial confidentiality. The financial  
6  
7 250 impact of changes in sales volumes will be estimated using publicly available information to  
8  
9 251 reflect expected profit margins within the industry. **Societal perspective** evaluation will use a  
10  
11 252 cost-utility analysis (CUA) to assess the efficiency of the intervention investment in relation  
12  
13 253 to future costs and savings to public and private bodies and health effects for the women, as  
14  
15 254 well as the impact on health inequalities. Health effects and related treatment and care costs  
16  
17 255 will be estimated using the published IMPACT<sub>NCD</sub> model, which simulates the incidence of  
18  
19 256 diabetes, coronary heart disease and stroke for a synthetic population with defined  
20  
21 257 demographic, socio-economic and clinical risk factors.<sup>36</sup> Future costs/savings and quality-  
22  
23 258 adjusted life years (QALYs) will be discounted using rates recommended in the National  
24  
25 259 Institute for Health and Care Excellence (NICE) reference case for public health guidelines at  
26  
27 260 the time of analysis: currently 3.5% per year for costs and health outcomes (3.5% for costs  
28  
29 261 and 1.5% for health outcomes in scenario analysis).<sup>37</sup>

## 262 2.7 Sample size calculations

263 The study will be powered to detect differences in the primary outcome (fresh fruit and  
264 vegetable purchasing) between women in the intervention and control groups during the 3-6  
265 months post-intervention period. We used data from our previous research on women in  
266 Hampshire who were the same age-range as the proposed participants of this study<sup>19</sup> and  
267 considered the supermarkets at which the women shopped as clusters to estimate a rho of 0.1  
268 as our intraclass correlation coefficient. We aim to detect a difference of 0.3 item/average bag  
269 of fruit/vegetables (1.5 portions) per week. Assuming a standard deviation of 0.7 item (3.5  
270 portions) per week as seen in the pilot data, 16 stores in each arm and 30 women per store  
271 provides 90% power at a 5% significance level (2-sided).



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2  
3 272 The study will also be powered to assess the secondary outcome of women's dietary quality.  
4  
5 273 Our previous research provided a rho of 0.1 as our intraclass correlation coefficient and a  
6  
7  
8 274 correlation coefficient of 0.8 for the means of women's dietary quality at the store level  
9  
10 275 between baseline and 2-year follow-up. Taking account of the clustering, and using the  
11  
12 276 method of Teerenstra<sup>38</sup> to adjust for the method of analysis planned (adjusting diet quality  
13  
14 277 score for baseline in the analyses), 16 stores in each arm with 30 women per store provides  
15  
16  
17 278 85% power at a 5% significance level (2-sided) to detect a difference in the diet quality  
18  
19 279 scores at follow-up of 0.23 standard deviations (SD). Additionally, assuming that half the  
20  
21 280 women have children aged 2-6 years, 16 stores in each arm will also provide 80% power to  
22  
23 281 detect a difference in the children's diet quality scores of 0.25SD using the methods  
24  
25 282 described above. Having fewer participants but retaining the full number of clusters has  
26  
27 283 relatively little impact on the anticipated power.<sup>39</sup> The recruitment plan will over-sample with  
28  
29 284 18 stores in each arm to account for potential store closure and up to 45 women per store to  
30  
31 285 account for attrition.  
32  
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## 36 286 *2.8 Statistical analysis*

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39

40 287 We will conduct analyses involving 3-level multilevel models, with women's weekly  
41  
42 288 purchasing data clustered within women, who are clustered within stores. Weekly purchasing  
43  
44 289 data are not normally distributed and therefore an alternative continuous distribution such as  
45  
46 290 the negative binomial distribution will be considered or a binary variable will be used. With  
47  
48 291 the data in 'long' format, an interaction between intervention group and time period will  
49  
50 292 indicate whether there is a difference in change in sales from the 3-month baseline period to  
51  
52 293 the 0-3 month and 3-6 month periods post-intervention between the control and intervention  
53  
54 294 stores. These models will be adjusted for sales from the 3-month baseline period as an  
55  
56 295 efficient analysis of the changes in purchasing taking account of regression to the mean.<sup>40</sup>  
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3 296 Effect modification by educational level will be assessed by including a multiplicative  
4  
5 297 interaction between intervention group and education level in the individual purchasing  
6  
7 298 models. If there is evidence of an interaction, stratified analyses will be performed to  
8  
9 299 determine the strength and direction of intervention effects for each level of educational  
10  
11 300 attainment.

12  
13  
14  
15 301 Women's dietary quality scores (SD) will be calculated at baseline, 3 and 6 months.  
16  
17 302 Multilevel linear regression models (with women clustered within stores) will be used with  
18  
19 303 dietary quality score as the outcome measure, intervention group as the exposure and baseline  
20  
21 304 diet scores included in the model to account for regression to the mean.<sup>40</sup> Confounders will  
22  
23 305 be determined by a Directed Acyclic Graph (DAG).<sup>41</sup> Analyses of other secondary outcomes  
24  
25 306 (i.e. daily fruit and vegetable intake and child's dietary quality) will adopt the same statistical  
26  
27 307 approach as that for women's dietary quality.

28  
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31  
32 308 Store sales data will be analysed using multilevel models to account for the clustering of  
33  
34 309 weeks within stores. Weekly sales data will be the outcome and will be transformed to  
35  
36 310 normality using Fisher-Yates transformations.<sup>42</sup> Analyses will use Interrupted Time Series  
37  
38 311 models<sup>43</sup> with confidence intervals calculated at the 3 and 6 month post-intervention  
39  
40 312 commencement time-points using the delta method.<sup>44</sup> Statistical analyses will be conducted  
41  
42 313 in Stata.<sup>45</sup>

## 43 44 45 46 47 314 *2.9 Process Evaluation*

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50  
51 315 A detailed process evaluation will be completed, following MRC guidance on process  
52  
53 316 evaluation,<sup>46</sup> to assess intervention implementation, mechanisms of impact and intervention  
54  
55 317 context. **Intervention fidelity** will be assessed in intervention and control stores through in-store  
56  
57 318 surveys conducted by trained fieldworkers using bespoke and published tools.<sup>18 47</sup> **Intervention**

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3 319 **exposure and reach** will be determined from loyalty card and questionnaire data.  
4  
5 320 **Mechanisms of impact** will be examined qualitatively through go-along interviews with a  
6  
7 321 purposive subsample of participants (n~30, 15 per arm). The go-along interviews will adopt a  
8  
9 322 symbolic interactionist ethnographic approach to examine the interpretations participants  
10  
11 323 assign to physical and social objects when food shopping.<sup>48</sup> This methodology combines  
12  
13 324 observation and interview, and will take the form of an accompanied food-shopping trip in  
14  
15 325 participants' study supermarket. Mechanisms of impact will also be examined quantitatively  
16  
17 326 using questionnaire data to conduct pathway analyses to ascertain possible mediating effects  
18  
19 327 of psychological agency<sup>49</sup> and/or food waste on the outcomes. **Intervention context** will be  
20  
21 328 assessed via semi-structured interviews with a purposive sample of policy makers, food retail  
22  
23 329 representatives, researchers and non-government organisations working with food retailers to  
24  
25 330 identify policy, retail business and macroeconomic factors that may have influenced  
26  
27 331 intervention implementation or impact. Information about the participants use for food  
28  
29 332 shopping and social influences on their food shopping choices collected during telephone  
30  
31 333 questionnaire, plus data from the in-store environment of the most frequently visited  
32  
33 334 supermarkets will be used to assess social and environmental contexts.  
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#### 41 335 *2.10 Patient and Public Involvement (PPI)*

42  
43 336 WRAPPED PPI activities will adopt a three-pronged strategy using an advisory PPI panel,  
44  
45 337 outreach to specific groups and online consultation; this enables representation of a range of  
46  
47 338 views. The PPI panel will help write outward facing materials (i.e. information and consent  
48  
49 339 forms, public friendly updates) and interpret the study findings. Our outreach activities will  
50  
51 340 engage supermarket staff, policy stakeholders and women to develop interview discussion  
52  
53 341 guides. Targeted consultations with websites (e.g. Mumsnet) will be used to identify changes  
54  
55 342 in target group needs and inform our dissemination activities. We will also invite two PPI  
56  
57 343 work with the study team to ensure methods are appropriate and issues are addressed as they  
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3 344 arise. They will help guide process evaluation data collection and analyses, interpret study  
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5 345 results, and assist with media engagement.  
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### 9 346 **3 Ethics and Dissemination**

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11  
12 347 Ethical approval for the WRAPPED study has been obtained from the University of  
13  
14 348 Southampton, Faculty of Medicine Ethics Committee (ID 20986.A4). This study will be  
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16  
17 349 conducted in accordance with the Declaration of Helsinki, Good Clinical Practice guidance,  
18  
19 350 Research Governance Framework for Health and Social Care and Data Protection  
20  
21 351 regulations. WRAPPED is registered with ClinicalTrials.gov (NCT03573973). An  
22  
23  
24 352 independent Study Steering Committee will provide strategic guidance, monitor progress and  
25  
26 353 assess professional conduct throughout the study duration. There is no Data Monitoring  
27  
28 354 Committee for this study because the risks to participants are minimal.  
29  
30

31  
32 355 This intervention has the potential to improve the diets and health of women of childbearing  
33  
34 356 age from disadvantaged backgrounds and provide cost-savings to the NHS; even modest  
35  
36 357 increases in fruit and vegetable intake (0.3-1.0 portion/day) could reduce risk of later  
37  
38 358 coronary heart disease by 4% and stroke by 5%.<sup>50 51</sup> Additionally, collecting primary and  
39  
40  
41 359 secondary outcome data at the individual level will provide greater understanding of which  
42  
43 360 individuals are susceptible to healthier food placement interventions and offer valuable  
44  
45 361 evidence for policy makers. The study findings will be disseminated through multiple  
46  
47  
48 362 pathways to ensure wide-reaching distribution to local, national and international audiences.  
49  
50 363 On completion of the trial, two manuscripts will describe the: i) results in relation to the  
51  
52 364 primary and secondary objectives, and ii) process evaluation findings. We will develop a  
53  
54 365 media strategy with our PPI members and retail collaborators to raise awareness of the role of  
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56  
57 366 supermarkets in promoting healthy food choices, produce policy briefings to inform  
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59 367 government action, and create guidance for academics and professionals, outlining successful  
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3 368 methods for research partnerships with food retailers to help improve the quality of existing  
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5 369 evidence.  
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9 370

### 11 371 **Acknowledgements**

14 372 We are grateful to Matt Downes, Hilary Berg, Neil Hayes and all the head-office and store  
15  
16 373 staff working for Iceland Foods Ltd who contributed to this study for their valued partnership  
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18  
19 374 and input.  
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21

### 22 375 **Source of funding**

25 376 This research and the authors of this paper are supported by the following funding sources:  
26  
27 377 National Institute for Health Research (NIHR) Public Health Research Programme  
28  
29 378 (17/44/46), NIHR Southampton Biomedical Research Centre, UK Medical Research Centre  
30  
31 379 and University of Southampton. Kylie Ball is supported by a Principal Research Fellowship  
32  
33 380 from the Australian National Health and Medical Research Council (NHMRC). The views  
34  
35 381 expressed in this publication are those of the author(s) and not necessarily those of the NHS,  
36  
37 382 the NIHR, the UK Department of Health and Social Care or NHMRC.  
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### 42 383 **Conflicts of interest statement**

45  
46 384 This study involves a non-financial collaboration with Iceland Foods Ltd. CV, SC, PD, CS,  
47  
48 385 JC, GM, JL and KB have no conflicts of interests to declare and no further financial  
49  
50 386 disclosures to make. JB and WL have received grant research support from Danone Nutricia  
51  
52 387 Early Life Nutrition. CC has received consultancy, lecture fees and honoraria from AMGEN,  
53  
54 388 GSK, Alliance for Better Bone Health, MSD, Eli Lilly, Pfizer, Novartis, Servier, Medtronic  
55  
56 389 and Roche. The study described in this manuscript is not related to these relationships.  
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3 390 **Contributor statement**  
4

5 391 CV and JB conceived the study, designed the intervention and evaluation, and wrote the first  
6  
7 392 draft of the study protocol and manuscript. SC, CC, KB, JL and GM contributed to the study  
8  
9 393 design and SC, JC, PD and CS aided development of the measures. SC conducted sample  
10  
11 394 size calculations and designed the statistical analyses with input from CV and JB; JL  
12  
13 395 designed the economic evaluation. All authors contributed to revising the manuscript and all  
14  
15 396 read and approved the final manuscript.  
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3 **List of figure legends**  
4

5 **Figure 1.** Flow chart for the WRAPPED (Women’s Responses to Adjusted Product  
6 Placement and its Effects on Diet) study  
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8  
9 **Figure 2.** Logic model for the WRAPPED study  
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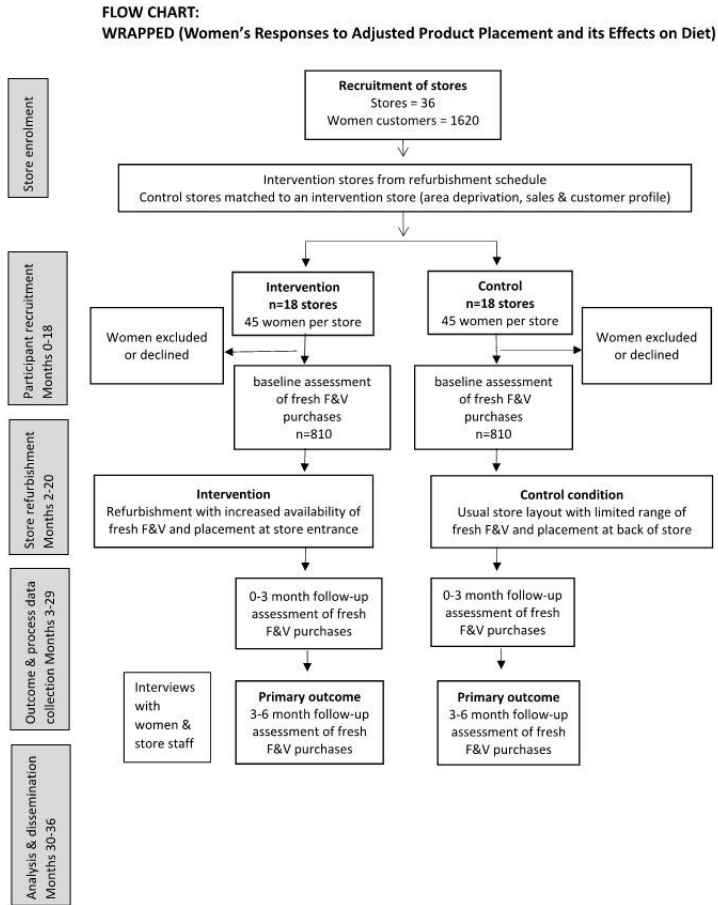


Figure 1. Flow chart for the WRAPPED (Women’s Responses to Adjusted Product Placement and its Effects on Diet) study

210x297mm (96 x 96 DPI)

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

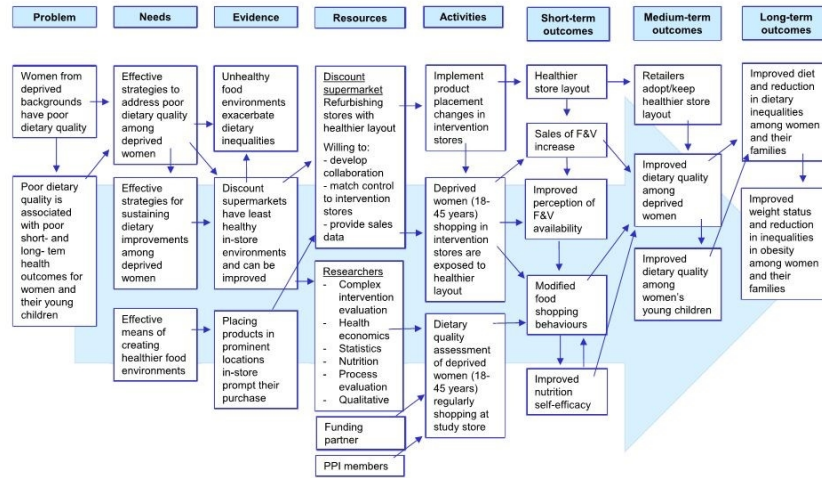


Figure 2. Logic model for the WRAPPED study

297x210mm (96 x 96 DPI)

# BMJ Open

## Protocol of a natural experiment to evaluate a supermarket intervention to improve food purchasing and dietary behaviours of women (WRAPPED study) in England: a prospective matched-controlled cluster design

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-036758.R1
Article Type:	Protocol
Date Submitted by the Author:	14-Jan-2020
Complete List of Authors:	Vogel, Christina; University of Southampton, MRC Lifecourse Epidemiology Unit Crozier, S; University of Southampton and Southampton University Hospitals NHS Trust, Institute of Developmental Sciences Dhuria, Preeti ; University of Southampton, MRC Lifecourse Epidemiology Unit Shand, Calum; University of Southampton, MRC Lifecourse Epidemiology Unit Lawrence, Wendy; University of Southampton, MRC Lifecourse Epidemiology Unit Cade, Janet; University of Leeds, School of Food Science and Nutrition Moon, Graham; University of Southampton, Geography and Environment Lord, Joanne; University of Southampton, Southampton Health Technology Assessments Centre Ball, Kylie; Deakin University, Centre for Physical Activity and Nutrition Research Cooper, Cyrus; University of Southampton and Southampton University Hospitals NHS Trust, MRC Lifecourse Epidemiology Unit Baird, Janis; University of Southampton, MRC Epidemiology Resource Centre
<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Health policy, Research methods
Keywords:	NUTRITION & DIETETICS, PUBLIC HEALTH, PREVENTIVE MEDICINE, HEALTH ECONOMICS

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3 **Protocol of a natural experiment to evaluate a supermarket intervention to improve**  
4 **food purchasing and dietary behaviours of women (WRAPPED study) in England: a**  
5 **prospective matched-controlled cluster design**  
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10 Christina Vogel<sup>1 2</sup>, Sarah Crozier<sup>1</sup>, Preeti Dhuria<sup>1</sup>, Calum Shand<sup>1</sup>, Wendy Lawrence<sup>1 2</sup>,  
11 Janet Cade<sup>6</sup>, Graham Moon<sup>4</sup>, Joanne Lord<sup>3</sup>, Kylie Ball<sup>5</sup>, Cyrus Cooper<sup>1 2</sup>, Janis Baird<sup>1 2</sup>  
12  
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14  
15

- 16 1. Medical Research Council Lifecourse Epidemiology Unit, University of  
17 Southampton, Southampton General Hospital, Tremona Road, Southampton SO16  
18 6YD United Kingdom  
19  
20 2. National Institute for Health Research Southampton Biomedical Research Centre,  
21 University of Southampton and University Hospital Southampton NHS Foundation  
22 Trust, Tremona Road, Southampton SO16 6YD United Kingdom  
23  
24 3. Southampton Health Technology Assessments Centre, Wessex Institute, University  
25 of Southampton, Alpha House, Enterprise Road, Southampton Science Park,  
26 Southampton, SO16 7NS United Kingdom  
27  
28 4. Geography and Environmental Science, University of Southampton, University  
29 Road, Southampton, SO17 1BJ United Kingdom  
30  
31 5. Institute of Physical Activity and Nutrition Research, Institute of Physical Activity  
32 and Nutrition Research, School of Exercise and Nutrition Sciences, Deakin  
33 University, 75 Pigdons Road, Geelong, Victoria 32165 Australia  
34  
35 6. School of Food Science and Nutrition, University of Leeds, Leeds LS2 9JT United  
36 Kingdom  
37

38  
39 **Correspondence to:** Christina Vogel, cv@mrc.soton.ac.uk, Tel: 023 8076 4042,  
40 University of Southampton, Southampton General Hospital, Tremona Road,  
41 Southampton SO16 6YD, UK  
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43 **Word count:** 3993/4000  
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47 **Key words:** Dietary behaviour, supermarkets, food purchasing, natural experiment, product  
48 placement, women  
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2  
3 **Abstract** (300/300 words)  
4

5 *Introduction:* Poor diet is a leading risk factor for non-communicable diseases and costs the  
6 NHS £5.8 billion annually. Product placement strategies used extensively in food outlets, like  
7 supermarkets, can influence customers' preferences. Policy makers, including the UK  
8 Government, are considering legislation to ensure placement strategies promote healthier  
9 food purchasing and dietary habits. High-quality scientific evidence is needed to inform  
10 future policy action. This study will assess whether healthier placement strategies in  
11 supermarkets improve household purchasing patterns and the diets of more than one  
12 household member.  
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23 *Methods and Analyses:* This natural experiment, with a prospective matched controlled  
24 cluster design, is set in discount supermarkets across England. The primary objective is to  
25 investigate whether enhanced placement of fresh fruit and vegetables improves household-  
26 level purchasing of these products after six months. Secondary objectives will examine: i)  
27 differences in intervention effects on purchasing by level of educational attainment, ii)  
28 intervention effects on the dietary quality of women and their young children, iii)  
29 intervention effects on store-level sales of fruit and vegetables, and iv) cost-effectiveness of  
30 the intervention from individual, retailer and societal perspectives. Up to 810 intervention  
31 and 810 control participants will be recruited from 18 intervention and 18 matched control  
32 stores. Eligible participants will be women aged 18-45 years, who hold a loyalty card and  
33 shop in a study store. Each control store will be matched to an intervention store on: i) sales  
34 profile, ii) neighbourhood deprivation and iii) customer profile. A detailed process evaluation  
35 will assess intervention implementation, mechanisms of impact and, social and  
36 environmental contexts.  
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55 *Ethics and Dissemination:* Ethical approval was obtained from the University of  
56 Southampton, Faculty of Medicine Ethics Committee (ID 20986.A5). Primary, secondary and  
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3 process evaluation results will be submitted for publication in peer-reviewed scientific  
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5 journals and shared with policy makers.  
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8 *Registration:* ClinicalTrials.gov registration: NCT03573973  
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15 *Strengths and limitations of this study*  
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- This study is unique; unlike current literature, it will provide evidence of product placement intervention effects from a cluster trial with adequate statistical power.
  - The outcomes of this study include household purchasing data from loyalty card use over a nine-month period, as well as dietary quality derived from food frequency questionnaires administered at four different time points.
  - This is the first supermarket placement study to provide dietary quality outcome data from more than one household member.
  - Randomisation of stores was not possible within this commercial setting, however, the criteria used to match stores increases the similarity of intervention and control stores and reduces effects of confounding.
  - This study tests a single component intervention; this is scientifically advantageous because it enables assessment of the isolated effects of this particular placement intervention, which improves the availability of fresh fruit and vegetables and positions them in the prominent front-of-store location.



## 1 Introduction

Poor diet is a leading risk factor for obesity and non-communicable diseases (NCDs).<sup>1</sup> In the UK, the cost of poor diet-related ill health to the NHS is £5.8 billion annually, and as many as 42,000 deaths could be prevented each year if people ate more fruit and vegetables.<sup>2</sup>

Inadequate intake of fruit and vegetables is of particular concern among low-income groups.<sup>3</sup>

Women represent an important target group for improving the diets of the broader population; they remain household food gatekeepers, dominating decisions about food shopping,<sup>4</sup> plus the short and long-term health of children is influenced by their mothers' food choices.<sup>5</sup> The Scientific Advisory Committee on Nutrition has expressed concern over the poor diets of young women in the UK and the impact on their children.<sup>6</sup> Improving the nutritional status of women before, during and after pregnancy is important for obesity prevention and is a priority in UK policy (Healthy Lives Healthy People; The Health of the 51%: Women).<sup>7 8</sup> Identifying strategies that support women of childbearing age, particularly those from disadvantaged backgrounds, to make healthy food choices could improve public health now and in the future.

Systematic reviews have shown that interventions providing information about healthy dietary behaviours alone are largely ineffective among disadvantaged groups and that campaigns such as '5-a-day' may even increase inequalities.<sup>9 10</sup> Evidence for interventions that are effective among disadvantaged populations remains limited, however, those addressing the broader environmental determinants of diet appear most promising.<sup>11</sup> It has been purported that information campaigns may be amplifying inequalities because they require high psychological agency, or conscious awareness of behavioural habits, which tends to be lower among disadvantaged groups.<sup>12</sup> In contrast, alterations to environmental stimuli can evoke unconscious reactions or improvements in health behaviours.<sup>13</sup> UK

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3 observational research supports this notion and suggests that unhealthy food environments  
4 may be exacerbating dietary inequalities. In Cambridgeshire, associations between exposure  
5 to fast food outlets and fast food intake were most pronounced among adults of low  
6 socioeconomic status.<sup>14</sup> In Hampshire, shopping at less healthy supermarkets, with poorer  
7 availability, pricing and placement of healthy foods, was associated with poor dietary quality  
8 among women who left school aged 16 years but not among those with degree  
9 qualifications.<sup>15</sup>

10  
11 Almost 90% of UK grocery sales occur within supermarkets<sup>16</sup> and the subtle use of  
12 marketing techniques influences the food choices of an almost captive market. A recent  
13 survey suggests that two-thirds of all placement marketing strategies used to promote food  
14 and beverages in UK supermarkets were for unhealthy products.<sup>17</sup> Additionally, discount and  
15 small supermarkets have been shown to have less healthy in-store environments than other  
16 supermarkets, including poorer placement of fresh fruit and vegetables.<sup>18</sup> This is concerning  
17 because these types of stores are used more regularly by disadvantaged families and younger  
18 adults who have poorer dietary behaviours.<sup>19 20</sup> The UK Government are considering banning  
19 the prominent placement of unhealthy foods in outlets like supermarkets.<sup>21</sup> Evaluating  
20 strategies in discount or small supermarkets that aim to improve the placement of fruit and  
21 vegetables could expand the government's intended policy and would aid understanding of  
22 their effects among a population with the most to gain from dietary improvements.

23  
24 Systematic reviews of supermarket interventions targeting the in-store environment, such as  
25 product placement strategies that alter the availability and positioning of healthy or unhealthy  
26 foods, show promising effects.<sup>22 23</sup> The majority of studies, however, have poor  
27 methodological quality. Many have not included a control group nor reported sample size  
28 calculations, and none included an adequate number of stores for a cluster design study.

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3 Additionally, very few studies assessed the effect of product placement changes on outcomes  
4  
5 at the individual level (i.e. customers' purchasing and dietary patterns), with most assessing  
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7 change at the store level (Shaw, Ntani, Baird, Vogel, unpublished). Not a single study  
8  
9 reported on cost-effectiveness.<sup>23</sup> Further high quality, adequately powered studies are needed  
10  
11 to quantify the effect of placement interventions in supermarkets. Studies that measure cost-  
12  
13 effectiveness and examine differential effects by socioeconomic status are particularly  
14  
15 important for policy makers. The collaboration with a discount supermarket chain established  
16  
17 for this study provides a unique opportunity to evaluate, on a large scale, the effectiveness  
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19 and cost-effectiveness of creating a healthier store layout in supermarkets frequently used by  
20  
21 disadvantaged families.  
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### 27 *1.1 Study objectives*

#### 28 29 30 31 1.1.1 Primary Objective:

32  
33 To assess whether increasing availability of fresh fruit and vegetables and positioning them at  
34  
35 the front of the store in discount supermarkets improves fresh fruit and vegetable purchasing  
36  
37 patterns 6 months after intervention commencement amongst women customers aged 18-45  
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39 compared to control customers.  
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#### 44 1.1.2 Secondary Objectives:

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47 i. To assess effect modification by educational attainment on women's change in fruit  
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49 and vegetable purchasing.
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52 ii. To assess how the intervention affects women's dietary quality and daily fruit and  
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54 vegetable intake, and the dietary quality of their young children.
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58 iii. To assess how the intervention influences weekly store sales of fruit and vegetables.  
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3 iv. To conduct an economic evaluation from individual, retailer and societal perspectives.  
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6 v. To conduct a detailed process evaluation to examine: i) intervention implementation  
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8 in each store and the exposure and reach to participants, ii) mechanisms of  
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10 intervention impact by exploring the experiences of participants and staff, and iii)  
11  
12 how contextual factors, such as social influences, spatial access to supermarkets and  
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14 government policy, influence intervention effects.  
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## 18 **2 Methods and Analyses**

### 19 *2.1 Study Design*

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22 The WRAPPED (Women's Responses to Adjusted Product Placement and its Effects on  
23  
24 Diet) study is a natural experiment with prospective matched controlled cluster design. It has  
25  
26 a 6-month intervention period and baseline, 0-3 month post and 3-6 month follow-up  
27  
28 assessments of intervention effects (see flow-chart, Figure 1).  
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### 35 *2.2 Study Setting*

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37  
38 WRAPPED focuses on women from disadvantaged backgrounds and will therefore sample  
39  
40 from customer who shop at stores of the collaborating discount supermarket chain situated in  
41  
42 more socioeconomically deprived neighbourhoods across England. The collaborating  
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44 supermarket has over 900 stores nationwide and holds approximately 2% of the grocery  
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46 market share in the UK.<sup>24</sup>  
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52 This study will sample 36 stores, 18 intervention and 18 control stores; allocation to  
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54 intervention condition will be at the store level. Intervention stores will be selected, in a  
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56 phased approach, from the collaborating supermarket's ongoing refurbishment programme.  
57  
58 Randomised controlled trial methodology in real-world supermarket research is limited  
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3 because it requires commitment that is problematic in this highly competitive, commercial  
4 setting. In WRAPPED, randomisation of stores is also not viable within the company's  
5  
6 business model. Consequently, control stores will be matched to an intervention store based  
7  
8 on: i) sales profile, ii) customer profile, and iii) neighbourhood deprivation (Index of Multiple  
9  
10 Deprivation).<sup>25</sup> Matching on these factors increases the similarity of intervention and control  
11  
12 stores and reduces effects of confounding. We will seek to select control stores located at  
13  
14 least 20 miles from an intervention store to reduce contamination effects of control women  
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16 shopping at intervention stores.  
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### 22 2.3 *Intervention and control conditions*

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26 The WRAPPED intervention incorporates both placement interventions from the typology of  
27  
28 interventions in proximal physical micro-environments (TIPPME): availability and  
29  
30 position.<sup>26</sup> The intervention creates a healthier store layout by expanding the produce section  
31  
32 to increase the availability of fresh fruit and vegetables, and positioning the section towards  
33  
34 the front of the store. The supermarket chain will implement the intervention and will cover  
35  
36 new display infrastructure and staff training costs (quality management etc). The intervention  
37  
38 will be implemented throughout the year, excluding the Christmas retail period, phased  
39  
40 across 22 months and commencing in 2019. The logic model (Figure 2) specifies the  
41  
42 intervention components and the route of impact for the short-, medium- and long-term. The  
43  
44 model specifies that disadvantaged women will be exposed to the in-store product placement  
45  
46 changes which will increase their purchasing of fresh fruit and vegetables (short-term  
47  
48 outcome) that in turn will improve their own and their young children's dietary quality  
49  
50 (medium-term outcomes) and subsequently reduce inequalities in diet and obesity (long-term  
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52 outcomes). This study will assess the short- and medium-term outcomes.  
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3 The control condition is the previous layout of stores with a limited range of fresh fruit and  
4 vegetables, placed at the back of the store. Both control and intervention stores will be  
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6 sampled from locations across England to improve generalisability.  
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#### 10 11 *2.4 Eligibility criteria*

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14 Participants will be women, aged 18-45 years, who hold a loyalty card with the study  
15 supermarket chain and have shopped in a study store in the 12-weeks before recruitment  
16 (according to loyalty card data). Shoppers who choose items in-store but opt for home  
17 delivery will be eligible. Women under the age of 18 or over 45 years, who do not hold a  
18 loyalty card or only shop online will not be eligible to participate.  
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#### 27 *2.5 Participant recruitment*

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30 Women from matched intervention and control stores will be recruited in the same period  
31 prior to the intervention implementation stores' refurbishment. Rolling recruitment over  
32 approximately two years will minimise bias from seasonal patterns of fruit and vegetable  
33 availability or consumption. Eligible women, identified from the loyalty card register, will be  
34 sent an invitation and information letter. Participants are not informed of the intervention.  
35 The letter invites them to participate in a study that is researching the food shopping and  
36 eating patterns of women aged 18-45 years. The letter will be sent by the supermarket to  
37 comply with data protection laws. Interested women will contact the study team via  
38  
39 Freephone number, text or email; they will be screened for eligibility and consented. In-store  
40 recruitment will also be used, whereby members of the research team approach women  
41 customers while shopping and provide them with a study information sheet. Women will  
42 register their interest with the researcher in-store and are phoned at a suitable time for them to  
43 be consented. This method proved effective at enhancing representation of disadvantaged  
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3 customers in a previous supermarket pricing trial.<sup>27</sup> Both intervention and control participants  
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5 will be recruited using these two methods which were identified as most successful during  
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7 feasibility testing.  
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11 To ensure compliance with data protection laws, participants who have provided informed  
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13 consent to the study team and completed the baseline survey will be sent an email from the  
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15 collaborating supermarket to seek explicit consent for their loyalty card data, covering the 9-  
16  
17 month study period, to be shared with the WRAPPED study team. Separate consent to take  
18  
19 part in the process evaluation sub-studies will be obtained. Participants can withdraw from  
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21 the study at any point without giving a reason and without affecting their relationship with  
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23 the collaborating supermarket.  
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28 All participants will be offered up to £30 Love2Shop vouchers as compensation for their time  
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30 given to the study. Our Patient and Public Involvement (PPI) representatives highlighted that  
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32 vouchers would be preferable to financial payment which may interfere with benefit  
33  
34 payments. Our incentive value is similar to an Australian supermarket pricing trial that used  
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36 incentives equivalent to \$75AUD to optimise recruitment and retention.<sup>28</sup> Distribution will  
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38 entail 1x £10 Love2Shop voucher after completion of baseline, 3 and 6 month questionnaires.  
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## 42 43 2.6 Outcome measures 44 45

46 This study is unique in its collection of individual-level sales data, as well as demographic  
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48 and dietary information, and is the first supermarket study to collect dietary data for more  
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50 than one family member.<sup>29</sup> Primary (purchasing) and secondary (store sales) outcome data  
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52 will be obtained through the supermarket's loyalty card scheme; other secondary outcome  
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54 (dietary quality, fruit and vegetable intake) and demographic data will be collected via  
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56 telephone surveys at baseline and 1, 3 and 6 months after intervention commencement. Using  
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3 telephone interviews can overcome low-literacy levels and enhance participation of  
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5 disadvantaged women.  
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### 7 8 2.6.1 Primary outcome 9

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11 The primary outcome is change in participant's weekly fruit and vegetable purchasing  
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13 patterns from baseline (3 months prior to refurbishment) to the 3-6 month period post-  
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15 refurbishment. Change in fruit and vegetable purchasing from baseline to the 0-3 month  
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17 period post-refurbishment will also be assessed to measure short-term purchasing effects.  
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21 These data will be obtained through the supermarket chain's loyalty card scheme and provide  
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23 information about the number of items for each product purchased at each store visit during  
24  
25 the study period. We will also examine sales of frozen fruit and vegetables (for substitution  
26  
27 effects). The research team will aggregate these data from each visit to a weekly structure for  
28  
29 analysis to enable our data to be presented as items (bags of fruit/vegetables because these  
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31 products are not sold singly at the collaborating supermarket chain) per household per week  
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33 which is comparable to analyses conducted in previous supermarket trials.<sup>28 30</sup>  
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### 37 38 2.6.2 Secondary Outcomes 39

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41 The secondary outcomes include women's and young children's dietary quality, women's  
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43 daily fruit and vegetable intake, weekly store sales and economic analyses. Measures of  
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45 women's and their young children's **dietary quality** will be assessed using published tools.<sup>31</sup>  
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48 <sup>32</sup> Participants will be asked to indicate how often in the previous month they (or their child)  
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50 consumed each of the 20 foods. A dietary quality score for each woman or child will be  
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52 calculated by multiplying their reported frequency of consumption of each of the 20 items  
53  
54 from their food frequency questionnaire (FFQ) by corresponding weightings derived from the  
55  
56 appropriate principal components analysis and then summing the results. Dietary scores will  
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58 be standardised to have a mean of 0 and standard deviation of 1. Higher diet scores represent  
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3 better dietary quality characterised by higher intakes of vegetables, fruit, water and  
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5 wholegrain bread and lower intakes of white bread, processed meats, fried/oven chips, crisps  
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7 and sugar. Women's daily **fruit and vegetable intake** will be measured via a 2-item tool.<sup>33</sup>  
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9  
10 We will assess change in daily portions of fruit and vegetables to quantify the independent  
11  
12 effect of this aspect of diet; this measure details change in the amount (quantity) of fruit and  
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14 vegetables eaten and will provide complementary data to the changes in frequency collected  
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16 by the FFQ. **Store sales data** will be provided from electronic transaction records aggregated  
17  
18 to the weekly level to enable comparison with previous work.<sup>34</sup> Weekly store sales data will  
19  
20 cover the periods from 3 months prior to refurbishment (baseline), and 0-3 and 3-6 months  
21  
22 post-refurbishment. Data will cover the same retail weeks for each matched pair of stores to  
23  
24 account for seasonal variation. The product categories created for the individual purchasing  
25  
26 data will also be used for the store sales data.  
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### 30 31 2.6.3 Economic evaluation 32

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34 The economic evaluation will be conducted from three perspectives, individual, retailer and  
35  
36 societal, and plans to estimate the costs and effects of the store refurbishment programme  
37  
38 over 5, 10 and 20-year time horizons using scenario analyses. These long-term projections  
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40 will require assumptions about the persistence of observed changes to shopping habits and  
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42 dietary behaviour beyond the 6-month study follow up. A range of possible scenarios will be  
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44 assessed, with waning of effects over periods from 6 months to 20 years. Individual and  
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46 retailer results will be presented as simple cost-consequence analysis (CCA) tables, with  
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48 estimates of monetary costs or savings shown in a 'balance sheet' alongside summary  
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50 statistics for other relevant outcomes. **Individual perspective** evaluation will use participant  
51  
52 survey data for food expenditure, time spent food shopping, fruit and vegetable waste as well  
53  
54 as travel costs to and from supermarkets; these data will be supplemented by loyalty card  
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56 data. **Retailer perspective** estimates will be generated through discussion with supermarket  
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3 staff. These may include the cost and expected lifespan of the intervention, ongoing costs  
4 such as additional refrigerator storage, extra produce deliveries, produce waste, changes in  
5 product group sales (displacement, substitutions and complements) and staff costs. Results  
6 will be presented at an aggregated level to respect commercial confidentiality. The financial  
7 impact of changes in sales volumes will be estimated using publicly available information to  
8 reflect expected profit margins within the industry. **Societal perspective** evaluation will use a  
9 cost-utility analysis (CUA) to assess the efficiency of the intervention investment in relation  
10 to future costs and savings to public and private bodies and health effects for the women, as  
11 well as the impact on health inequalities. Health effects and related treatment and care costs  
12 will be estimated using the published IMPACT<sub>NCD</sub> model, which simulates the incidence of  
13 diabetes, coronary heart disease and stroke for a synthetic population with defined  
14 demographic, socio-economic and clinical risk factors.<sup>35</sup> Future costs/savings and quality-  
15 adjusted life years (QALYs) will be discounted using rates recommended in the National  
16 Institute for Health and Care Excellence (NICE) reference case for public health guidelines at  
17 the time of analysis: currently 3.5% per year for costs and health outcomes (3.5% for costs  
18 and 1.5% for health outcomes in scenario analysis).<sup>36</sup>

## 2.7 Sample size calculations

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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 period. We used data from our previous research on women in Hampshire who were the same age-range as the proposed participants of this study<sup>19</sup> 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 item/average bag of fruit/vegetables (1.5 portions) per week. Assuming a standard deviation of 0.7 item (3.5

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3 portions) per week as seen in the pilot data, 16 stores in each arm and 30 women per store  
4  
5 provides 90% power at a 5% significance level (2-sided).  
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8  
9 The study will also be powered to assess the secondary outcome of women's dietary quality.

10  
11 Our previous research provided a rho of 0.1 as our intraclass correlation coefficient and a  
12  
13 correlation coefficient of 0.8 for the means of women's dietary quality at the store level  
14  
15 between baseline and 2-year follow-up. Taking account of the clustering, and using the  
16  
17 method of Teerenstra<sup>37</sup> to adjust for the method of analysis planned (adjusting diet quality  
18  
19 score for baseline in the analyses), 16 stores in each arm with 30 women per store provides  
20  
21 85% power at a 5% significance level (2-sided) to detect a difference in the diet quality  
22  
23 scores at follow-up of 0.23 standard deviations (SD). Additionally, assuming that half the  
24  
25 women have children aged 2-6 years, 16 stores in each arm will also provide 80% power to  
26  
27 detect a difference in the children's diet quality scores of 0.25SD using the methods  
28  
29 described above. Having fewer participants but retaining the full number of clusters has  
30  
31 relatively little impact on the anticipated power.<sup>38</sup> The recruitment plan will over-sample with  
32  
33 18 stores in each arm to account for potential store closure and up to 45 women per store to  
34  
35 account for attrition.  
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## 41 42 2.8 *Statistical analysis*

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44

45 We will conduct analyses involving 3-level multilevel models, with women's weekly  
46  
47 purchasing data clustered within women, who are clustered within stores. Weekly purchasing  
48  
49 data are not normally distributed and therefore an alternative continuous distribution such as  
50  
51 the negative binomial distribution will be considered or a binary variable will be used. With  
52  
53 the data in 'long' format, an interaction between intervention group and time period will  
54  
55 indicate whether there is a difference in change in sales from the 3-month baseline period to  
56  
57 the 0-3 month and 3-6 month periods post-intervention between the control and intervention  
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3 stores. These models will be adjusted for sales from the 3-month baseline period as an  
4  
5 efficient analysis of the changes in purchasing taking account of regression to the mean.<sup>39</sup>  
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8  
9 Effect modification by educational level will be assessed by including a multiplicative  
10  
11 interaction between intervention group and education level in the individual purchasing  
12  
13 models. If there is evidence of an interaction, stratified analyses will be performed to  
14  
15 determine the strength and direction of intervention effects for each level of educational  
16  
17 attainment.  
18  
19

20  
21 Women's dietary quality scores (SD) will be calculated at baseline, 3 and 6 months.  
22

23  
24 Multilevel linear regression models (with women clustered within stores) will be used with  
25  
26 dietary quality score as the outcome measure, intervention group as the exposure and baseline  
27  
28 diet scores included in the model to account for regression to the mean.<sup>39</sup> Confounders will  
29  
30 be determined by a Directed Acyclic Graph (DAG).<sup>40</sup> Analyses of other secondary outcomes  
31  
32 (i.e. daily fruit and vegetable intake and child's dietary quality) will adopt the same statistical  
33  
34 approach as that for women's dietary quality.  
35  
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38  
39 Store sales data will be analysed using multilevel models to account for the clustering of  
40  
41 weeks within stores. Weekly sales data will be the outcome and will be transformed to  
42  
43 normality using Fisher-Yates transformations.<sup>41</sup> Analyses will use Interrupted Time Series  
44  
45 models<sup>42</sup> with confidence intervals calculated at the 3 and 6 month post-intervention  
46  
47 commencement time-points using the delta method.<sup>43</sup> Statistical analyses will be conducted  
48  
49 in Stata.<sup>44</sup>  
50  
51

## 52 53 *2.9 Process Evaluation*

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56  
57 A detailed process evaluation will be completed, following MRC guidance on process  
58  
59 evaluation,<sup>45</sup> to assess intervention implementation, mechanisms of impact and intervention  
60

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3 context. **Intervention fidelity** will be assessed in intervention and control stores through in-store  
4 surveys conducted by trained fieldworkers using bespoke and published tools.<sup>18 46</sup> **Intervention**  
5  
6 **exposure and reach** will be determined from loyalty card and questionnaire data.  
7  
8  
9  
10 **Mechanisms of impact** will be examined qualitatively through go-along interviews with a  
11 purposive subsample of participants (n~30, 15 per arm). The go-along interviews will adopt a  
12 symbolic interactionist ethnographic approach to examine the interpretations participants  
13 assign to physical and social objects when food shopping.<sup>47</sup> This methodology combines  
14 observation and interview, and will take the form of an accompanied food-shopping trip in  
15 participants' study supermarket. Mechanisms of impact will also be examined quantitatively  
16 using questionnaire data to conduct pathway analyses to ascertain possible mediating effects  
17 of psychological agency<sup>48</sup> and/or food waste on the outcomes. **Intervention context** will be  
18 assessed via semi-structured interviews with a purposive sample of policy makers, food retail  
19 representatives, researchers and non-government organisations working with food retailers to  
20 identify policy, retail business and macroeconomic factors that may have influenced  
21 intervention implementation or impact. Information about the participants use for food  
22 shopping and social influences on their food shopping choices collected during telephone  
23 questionnaire, plus data from the in-store environment of the most frequently visited  
24 supermarkets will be used to assess social and environmental contexts.  
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#### 45 *2.10 Patient and Public Involvement (PPI)*

46 WRAPPED PPI activities will adopt a three-pronged strategy using an advisory PPI panel,  
47 outreach to specific groups and online consultation; this enables representation of a range of  
48 views. The PPI panel will help write outward facing materials (i.e. information and consent  
49 forms, public friendly updates) and interpret the study findings. Our outreach activities will  
50 engage supermarket staff, policy stakeholders and women to develop interview discussion  
51 guides. Targeted consultations with websites (e.g. Mumsnet) will be used to identify changes  
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3 in target group needs and inform our dissemination activities. We will also invite two PPI  
4  
5 work with the study team to ensure methods are appropriate and issues are addressed as they  
6  
7 arise. They will help guide process evaluation data collection and analyses, interpret study  
8  
9 results, and assist with media engagement.  
10  
11

### 12 13 **3 Ethics and Dissemination** 14 15

16  
17 Ethical approval for the WRAPPED study has been obtained from the University of  
18  
19 Southampton, Faculty of Medicine Ethics Committee (ID 20986.A4). This study will be  
20  
21 conducted in accordance with the Declaration of Helsinki, Good Clinical Practice guidance,  
22  
23 Research Governance Framework for Health and Social Care and Data Protection  
24  
25 regulations. WRAPPED is registered with ClinicalTrials.gov (NCT03573973). An  
26  
27 independent Study Steering Committee will provide strategic guidance, monitor progress and  
28  
29 assess professional conduct throughout the study duration. There is no Data Monitoring  
30  
31 Committee for this study because the risks to participants are minimal.  
32  
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36  
37 This intervention has the potential to improve the diets and health of women of childbearing  
38  
39 age from disadvantaged backgrounds and provide cost-savings to the NHS; even modest  
40  
41 increases in fruit and vegetable intake (0.3-1.0 portion/day) could reduce risk of later  
42  
43 coronary heart disease by 4% and stroke by 5%.<sup>49 50</sup> Additionally, collecting primary and  
44  
45 secondary outcome data at the individual level will provide greater understanding of which  
46  
47 individuals are susceptible to healthier food placement interventions and offer valuable  
48  
49 evidence for policy makers. The study findings will be disseminated through multiple  
50  
51 pathways to ensure wide-reaching distribution to local, national and international audiences.  
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53  
54 On completion of the trial, two manuscripts will describe the: i) results in relation to the  
55  
56 primary and secondary objectives, and ii) process evaluation findings. We will develop a  
57  
58 media strategy with our PPI members and retail collaborators to raise awareness of the role of  
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3 supermarkets in promoting healthy food choices, produce policy briefings to inform  
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5 government action, and create guidance for academics and professionals, outlining successful  
6  
7 methods for research partnerships with food retailers to help improve the quality of existing  
8  
9 evidence.  
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## 15 **Acknowledgements**

16  
17  
18 We are grateful to Matt Downes, Hilary Berg, Neil Hayes and all the head-office and store  
19  
20 staff working for Iceland Foods Ltd who contributed to this study for their valued partnership  
21  
22 and input. Iceland Foods Ltd is known as a British value supermarket chain in the retail  
23  
24 sector but is classified as a discount supermarket in the scientific literature.  
25  
26  
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28

## 29 **Source of funding**

30  
31  
32 This research and the authors of this paper are supported by the following funding sources:  
33  
34 National Institute for Health Research (NIHR) Public Health Research Programme  
35  
36 (17/44/46), NIHR Southampton Biomedical Research Centre, UK Medical Research Centre  
37  
38 and University of Southampton. Kylie Ball is supported by a Principal Research Fellowship  
39  
40 from the Australian National Health and Medical Research Council (NHMRC). The views  
41  
42 expressed in this publication are those of the author(s) and not necessarily those of the NHS,  
43  
44 the NIHR, the UK Department of Health and Social Care or NHMRC.  
45  
46  
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48

## 49 **Conflicts of interest statement**

50  
51  
52 This study involves a non-financial collaboration with Iceland Foods Ltd. CV, SC, PD, CS,  
53  
54 JC, GM, JL and KB have no conflicts of interests to declare and no further financial  
55  
56 disclosures to make. JB and WL have received grant research support from Danone Nutricia  
57  
58 Early Life Nutrition. CC has received consultancy, lecture fees and honoraria from AMGEN,  
59  
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3 GSK, Alliance for Better Bone Health, MSD, Eli Lilly, Pfizer, Novartis, Servier, Medtronic  
4 and Roche. The study described in this manuscript is not related to these relationships.  
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7

## 8 9 **Contributor statement**

10  
11 CV and JB conceived the study, designed the intervention and evaluation, and wrote the first  
12 draft of the study protocol and manuscript. SC, CC, KB, JL and GM contributed to the study  
13 design and SC, JC, WL, PD and CS aided development of the measures. SC conducted  
14 sample size calculations and designed the statistical analyses with input from CV and JB; JL  
15 designed the economic evaluation and CV, WL and PD designed the qualitative methods. All  
16 authors contributed to revising the manuscript and all read and approved the final manuscript.  
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2  
3 **List of figure legends**  
4

5 **Figure 1.** Flow chart for the WRAPPED (Women's Responses to Adjusted Product  
6 Placement and its Effects on Diet) study  
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8  
9 **Figure 2.** Logic model for the WRAPPED study  
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For peer review only

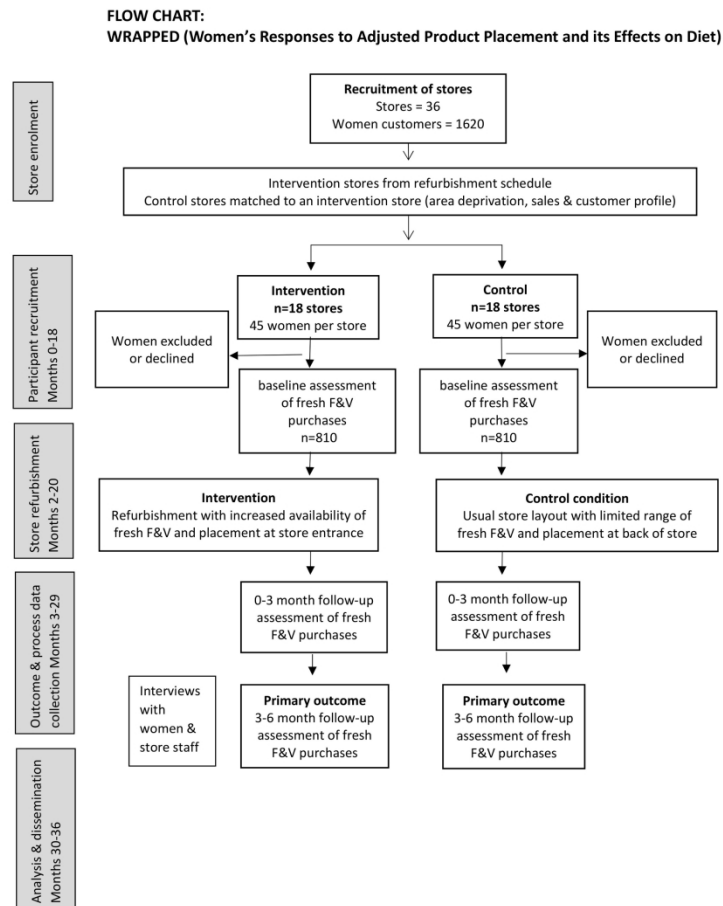


Figure 1. Flow chart for the WRAPPED (Women's Responses to Adjusted Product Placement and its Effects on Diet) study

209x296mm (300 x 300 DPI)

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

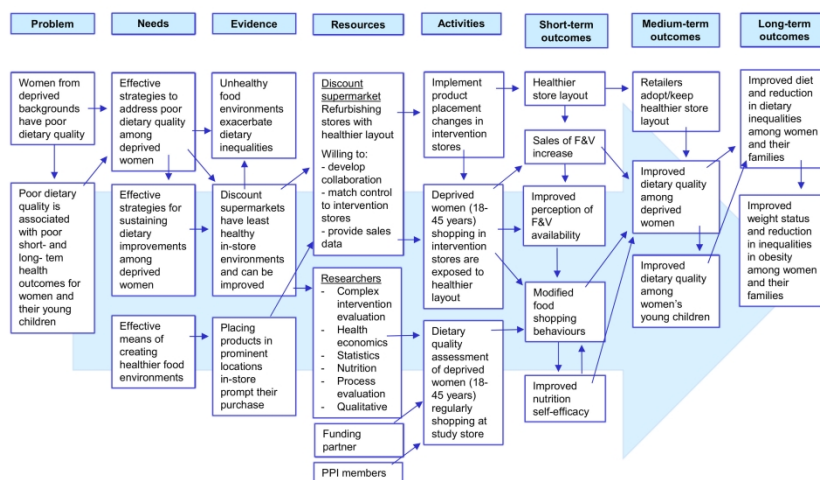


Figure 2. Logic model for the WRAPPED study

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