



The effect of a relative availability intervention on the sale of vegetarian meals in a frozen ready-meal retailer

Intervention and Evaluation Plan

This document provides a detailed description of an intervention that the SALIENT consortium (led by the University of Oxford researchers – 'the trial team' and a frozen ready-meal retailer, COOK, will deliver in partnerships in 2024.

Updated 12 August 2024.

Administrative information

Sponsor	University of Oxford Radcliffe Primary Care Building, Radcliffe Observatory Quarter, Woodstock Road, OX2 6GG United Kingdom <u>RGEA.Sponsor@admin.ox.ac.uk</u> +44(0) 1865 617855							
Funder	Economic and Social Research Council (ESRC), Ref: ES/Y00311X/1							
Principal co-investigators	Professor Peter Scarborough and Professor Martin White							
Trial team	Dr Jessica Renzella, Dr Josephine Gondwe, Dr Asha Kaur, Dr Rachel Pechey, Alice O'Hagan, Darren Hilliard, Dr Michael Clark, Dr Sarah Mounsey, Dr David Dearlove, Dr Bisola Osifowora, Dr Emma Frew, Prof Jean Adams, Prof Martin White and Prof Peter Scarborough on behalf of the SALIENT Consortium.							





Table of contents

Summary
What is already known?
What does this study add?
How will we evaluate success?
Key terms
Background and rationale
Research questions
Hypothesis
Theory of Change
Methods
Setting
Study design
Study intervention
Inclusion criteria10
Randomisation11
Outcomes11
Statistical analyses
Data Management
Trial monitoring
Process evaluation
Economic evaluation and modelling20
Ethical approval21
Proposed timeline
Dissemination opportunities23
REFERENCES
APPENDIX 125





Summary

What is already known?

- People's health and the environment are affected by dietary choices, as certain diets have higher environmental impacts than others and contribute to ill health.
- It is crucial to increase fruit and vegetable consumption and reduce meat consumption to promote better health outcomes and a more sustainable environment.
- Food selection can be influenced by changing food environments (e.g., cafeterias and food retailers).
- Findings from experiments conducted in university and worksite canteens suggest that increasing the availability of vegetarian food increases its sales. This, in turn, may help increase the consumption of these foods.
- More evidence from real-world retail settings is needed.

What does this study add?

• To the best of our knowledge, no previous randomised studies have investigated interventions that increase the availability of vegetarian meal facings in retail settings.

How will we evaluate success?

- We will conduct a stepped-wedged randomised controlled trial in five COOK stores over six weeks to measure the effect of the intervention on meal sales.
- We will conduct a process evaluation of the intervention to understand how it was implemented and its acceptability in a real-world setting and to identify what improvements could be made in the future.
- We will conduct an economic evaluation of the intervention to determine intervention costs (i.e. cost-benefit ratio) in relation to the projected impact on population health and the environment.

Policy relevance

- This trial will reveal whether changing a retail environment to increase the availability of vegetarian meals influences purchasing behaviour. We hypothesise that the intervention will reduce the environmental impact of meal sales and increase the nutritional quality of meal sales.
- If the intervention appears to be promising in this setting, then this would suggest that policy action aimed at increasing the availability of vegetarian meals in all retail settings (e.g. by setting mandatory quotas for plant-based options) could improve health and reduce environmental impact simultaneously.







Key terms

Facings: Facings refer to the number/proportion of labels that are viewable. For example, if 16 products are visible at the top of each pile within a chest freezer, and behind each of the 16 products is a stack of 10 identical items, the number of facings is 16. If there are two piles of macaroni cheese, each consisting of 5 products, then that will count as 2 facings.

Chef's Wall: The Chef's wall refers to a group of 5 freezers (in 18 freezer stores) or 6 freezers (in 19 freezer stores) containing the COOK core product range, accounting for approximately 44% of sales. These products are contained in freezers that are usually grouped together. For the larger 18/19 freezer stores, it is very likely that they will be grouped together. For smaller stores, there may be some variation in the position of the different freezers. The term "Chef's wall" is an internal term used by COOK – it is not communicated to customers.

Vegetarian diet: A diet that excludes meat, poultry, seafood and, sometimes, animal-source foods (e.g., eggs, milk, etc., are not consumed in vegan diets). In this protocol, "vegetarian" will be used to refer to both vegetarian and vegan meals.

Stepped Wedge Randomised Controlled Trial (RCT): A type of randomised controlled trial where an intervention is rolled out across multiple sites (i.e. stores) sequentially over a set time period with all clusters exposed to the intervention by the end of the study period(1).

Intervention stores: Refers to COOK stores where the intervention, namely the increase in the facings of vegetarian meals, will be implemented.

Non-intervention stores: Refers to COOK stores where the specified intervention, involving the increase in the number of facings of vegetarian meals, will not be implemented.

PRIMEtime model: A closed-cohort proportional multi-state life table model that estimates changes in health outcomes (both mortality and morbidity), NHS costs, social care costs and broader societal costs due to population changes in diet and physical activity (2).

NVivo: Software program used for qualitative and mixed methods research.

R: Software program used for statistical analyses (3).







Background and rationale

The UK food system is neither sufficiently healthy nor sustainable. Poor diet is the second-leading cause of death and ill health in the UK(4). This is due to the effects of poor diets (i.e., obesity and high blood pressure) on non-communicable diseases such as cardiovascular disease, diabetes and cancer. Previous research has shown that increased consumption of red and processed meat is associated with colorectal cancer (5), diabetes and ischemic heart disease (6) compared to lower meat intake. Additionally, food production is the leading cause of biodiversity loss (7) and water pollution (8) and accounts for approximately 34% of global greenhouse emissions (9). Animal production is particularly damaging to the environment, accounting for nearly 60% of greenhouse gas emissions from food production (10). In the UK, food production accounts for one-fifth of the country's total greenhouse emissions (11).

The UK government commissioned a National Food Strategy (NFS) to plot a course towards healthy, sustainable food provision and consumption. According to the NFS, a 30% rise in fruit and vegetable consumption, a 50% increase in fibre intake, and a 30% reduction in meat consumption in the average UK diet by 2032 could contribute to fulfilling our health and climate-related goals (for example, the 5th carbon budget and 30x30 nature commitment) (12).

Previous literature suggests that shaping environments can influence food selection to cue consumers' behaviour (13). For example, a meta-analysis of three studies in a Cochrane review showed that reducing the availability of less healthy food options reduced their selection (standardised mean difference: -1.13, 95% CI: -1.9, -0.37, I²=64%)(14). This meta-analysis included studies conducted in various settings: one was in a preschool where they changed the variety of fruits and vegetables available (15), another was in a worksite cafeteria where they increased the proportion of healthier food options (16), and the last was in schools where they boosted the availability of low-calorie products (17). However, the confidence intervals were wide, and the total sample size that informed this meta-analysis was small (154 participants) and did not exceed the optimal information size (i.e., the number of participants generated by a conventional sample size calculation for a single adequately powered trial powered conservatively to detect a small effect size) (14). Additionally, none of these studies were carried out in a retail setting, so their relevance to real-world applications in retail is limited.

Other studies suggest that offering more vegetarian meals in university and worksite cafeterias leads to higher sales of these meals. For example, one study found that doubling the proportion of vegetarian meals offered at a university cafeteria increased vegetarian sales from 19.1% (95% CI: 15.1%, 23.9%) to 26.9% (95% CI: 21.5%, 33.1%) (18). Another natural experiment in a different university cafeteria found that increasing the proportion of meat-free meals (from one option out of three to two options out of three) decreased the proportion of sales of meat options (-19.9 percentage points, 95% CI: -25.2, -14.6) (19).

One online randomised controlled study of 2205 UK adults found that reducing meat-free options from 50 to 25% reduced participants' selection of meat-free options (OR: 0.35, 95% CI: 0.26, 0.46) while increasing meat-free options from 50 to 75% increased meat-free selections (OR: 2.43, 95% CI: 1.94, 3.04)(19). The participant selection in this study aimed to be more representative than the previous two studies discussed above. However, since the study was hypothetical and no actual money was involved, it's uncertain whether the participants' choices would have been the same in a real-world scenario.







In retail settings, Veganuary (a campaign that encourages people to try a vegan lifestyle for the month of January) promotes an increase in plant-based purchases (20, 21). Trewern et al. analysed a natural experiment across 170 supermarkets and convenience stores during Veganuary, where the accessibility, availability, visibility, and affordability of plant-based products were enhanced (20). Their findings revealed that sales of plant-based products were significantly higher during the intervention period compared to pre-intervention (+57%, IRR 1.56, (95% CI: 1.54, 1.58)). This study offered real-world evidence from a retail setting, demonstrating a combined impact of increased availability and other contributing factors (e.g., increased visibility and accessibility of target products). Additionally, during the post-intervention period (8 weeks), plant-based sales were lower than in the intervention period but higher than in pre-intervention, suggesting the impact of the intervention was sustained (+15%, IRR 1·14 (95% CI 1·13, 1·16)), at least in the short-term. Nevertheless, this study was conducted during Veganuary, a time dedicated to boosting vegetarian sales through promotional efforts. It is important to assess whether similar effects would occur in other retail environments outside of promotional periods when sales follow a more typical pattern. It was also non-randomised randomised, so it is not possible to remove the risk of confounding results by unmeasured variables.

The SALIENT project aims to co-design and test interventions promoting healthier and more sustainable diets by working with the public, policymakers and food system partners such as COOK. COOK is a frozen ready-meal manufacturer and retailer in the UK with over 90 stores nationwide. The information generated from trials will help us understand the effectiveness of interventions, how they work and to what extent they can be applied across different settings.

The trial we will run with COOK will study the impact of increasing the relative availability of vegetarian ready meals by increasing vegetarian facings in freezers and, for some stores, simultaneously decreasing meat facings. The findings will contribute new knowledge about how altering the availability of vegetarian options can impact purchase choices in real-world retail settings. Furthermore, we will conduct a process evaluation to assess the acceptability and fidelity of the intervention and its implementation.

The findings of this trial will enhance our understanding of effective interventions for promoting healthier and more sustainable eating. Moreover, we aim to learn valuable lessons on how to expand the reach of these interventions to achieve maximum impact across the food system.

Research questions

- 1. What is the impact of increasing the relative availability of vegetarian ready-meals on display on the *proportion* of vegetarian ready-meal unit sales?
- 2. What is the impact of increasing the relative availability of vegetarian ready-meals on display on *total* ready-meal sales?

Hypothesis

Increasing the relative availability of vegetarian ready meals out of total options increases the proportion of their unit sales without changing overall sales of ready meals in the intervention





periods compared to the control periods. These changes will reduce the environmental impact of ready-meal sales and increase their nutritional quality.



Theory of Change

I

INTERVENTION	MECHANISMS	POTENTIAL OUTCOMES	
		Direct outcomes Indirect outcomes	Wider outcomes
	Increased salience and visibility More vegetarian meals on display may cue customers to buy vegetarian option	sales during the intervention period Increased vegetarian purchases and consumption at home and from other stores	Other retailers follow suit nd increase their range of healthier and more sustainable ready meals
	Social norm More vegetarian meals on display may convey that preferences for vegetarian meals are more common		Societal norms towards egetarian meals become more positive
Increase in the facings of vegetarian ready meals	Price Assuming vegetarian meals are priced		ositive environmental and alth outcomes for people
on the Chef's wall from	lower than meat-based meals, this may drive purchase	Revenue gains for COOK ²	and planet
~30% to 44- 45% in		Customers may buy meat-based products from UNDESIRED OUTCOMES	
45% in freezers	Liking/preference ¹ Increased likelihood that a vegetarian	other freezers (not Chef's wall) Increased consumption of meat- based products from other stores	Other retailers do not follow suit to increase
	meal is the most liked meal on offer Positioning ¹ Increased likelihood that a uppotentian	No (or negative) impact on environmental and health outcomes if vegetarian meals are less Reduced willingness for COOK to engage in future interventions	their range of healthier and more sustainable ready meals
	Increased likelihood that a vegetarian meal is positioned in a mixed freezer and draws customers' attention or makes a meal easier to access	sustainable and healthy than meat meals ⁴ Potential revenue loss from unsold vegetarian meals thereby affecting total sales May increase production of meat- based products following no or negative intervention outcomes	

SALIENT

Food system trials for healthier people and planet

G





Theory of change continued

Assumptions

1 - This depends on how the intervention is implemented (i.e. if there is an increase in both variety and volume of products).
2 - Revenue gains may occur if vegetarian meals have larger profit margins (e.g. due to cheaper ingredients) than meat meals.
3 - This depends on the shelf life of products.
4 - Although vegetarian meals are, on average, healthier and more sustainable than meat-based meals, the specific vegetarian dishes sold during the trial may not be, for example, if they contain high amounts of dairy products, replacing meals based on healthier and more sustainable meats like chicken.

Methods

Setting

COOK is a frozen ready-meal manufacturer and retailer in the UK with over 90 stores nationwide, including 25 franchise stores. COOK is also a certified B Corporation, aiming to meet high social and environmental performance standards, transparency and accountability in their business. A standard shop has, on average, 18 freezers (larger stores consist of 19 or 20 freezers) and caters to different portion sizes (1, 2, 4, and 8) for different sizes of households and events. In addition to their own stores, COOK also stocks its products in freezers in Co-ops, farm shops and other concessionary stores. The largest customer segment is 30-64 years old, and sales are highest around Easter and Christmas. Approximately 19% of COOK's ready-meal sales are vegetarian and vegan and they aspire to increase the sales of these products to 30%. The Chef's Wall range (where the intervention will take place) accounts for 44% of sales across all COOK shops, of which 23% are from vegetarian and vegan products (herein all termed vegetarian). The vegetarian products take up between 29% and 33% of Chef's wall freezer space. All these figures are total for all shops from the first 31 weeks of the 2023 financial year.

Study design

We will conduct a stepped wedge randomised controlled trial (RCT) in COOK's two 18- and three 19freezer stores over six weeks in the Summer of 2024. A stepped wedge RCT was chosen to meet the statistical and pragmatic needs of the trial. A stepped wedge design allows us to conduct a wellpowered trial with fewer sites compared to what a parallel RCT would require. This is because the intervention stores also act as their own controls. The five stores included in this trial are all company-owned. Based on pilot data shared by COOK, ~31% of vegetarian facings account for ~23% of the sales on the Chef's wall; therefore, using this ratio and increasing the proportion of vegetarian ready meals from ~31% to 44-45% in five stores will provide 88% power to detect an expected 9 percentage point increase (i.e., from ~23% to ~32%) of sales of vegetarian ready meals in a stepped wedge trial with five participating stores.

The five stores in the study will be placed into an order randomly. This random order will determine when the stores introduce the intervention (i.e. increase vegetarian facings on the Chef's wall to 44







% in 18 freezer- and 45% in 19 freezer stores). None of the stores will introduce the intervention in the first week of the trial (intervention) period. In the second week, store 1 will introduce the intervention. In the third week, store 2 will introduce the intervention, and so on, until all stores have introduced the intervention (see Figure 1). After-the intervention is introduced, each store-will consistently provide the intervention every day until the end of the study. This means that the stores will each provide the intervention for a different amount of time. During the intervention, COOK will not change the variety of meals but rather the proportion of vegetarian meal facings. Vegetarian meals will maintain their current prices as determined by COOK (i.e. the same as non-intervention stores). Some vegetarian meals will be mixed with meat-based meals (i.e. in the same freezers) with no in-store point-of-sale communications to avoid cueing customers. Customers can identify if a meal is vegetarian through explicit labelling on the packaging or the presence of vegetarian ingredients.

In addition to collecting data from intervention stores, sales data from five COOK stores meeting the inclusion criteria but not participating in the trial (non-intervention stores) will be analysed to assess the background trends in vegetarian meal purchasing during the study period. These stores will be matched based on the proportion of vegetarian meals (specifically, having over 20% of their ready-meals on the Chef's wall as vegetarian) and freezer capacity (requiring a minimum of 18 freezers). The sales data from these stores will be used to test for non-linear time trends in the outcome variables, which could bias the results of a stepped wedge trial (see **Statistical analyses**).

During baseline and intervention periods, other activities, promotions, or campaigns may be running across stores as part of the company's normal business operations. This information will be included in the sales data that we will collect from COOK. We will record such activities through monitoring calls and site visits (situational analysis). Notably, COOK will not run counteracting promotions that may affect the conduct of the trial for example, a price promotion of meat-based meals. As part of our process evaluation (described later), we will visit intervention stores and interview the COOK store staff, including key decision makers, on the conduct of the trial.

Study intervention

The intervention is increasing the relative availability of vegetarian products by increasing the proportion of vegetarian freezer facings on the Chef's Wall in the participating COOK stores.

The intervention will be implemented in two 18- and three 19-freezer stores. The vegetarian facings will be increased to 44% in the 18 freezer stores and 45% in the 19 freezer stores. Additionally, some meat facings will be reduced in the 18 freezer stores. These products will still be available for purchase upon request (available 'out the back').

The trial is planned to be implemented from 29 July to 8 September 2024, as this is when sales are typically lower than other periods (e.g., Easter and Christmas, which represent peak sale periods for COOK), and, therefore, the intervention poses less of a commercial risk for COOK. The presumably low sales may affect the ability to detect significant changes in vegetarian ready-meal sales, and this is a limitation of this trial. Throughout the trial period, the study team will conduct at least one inperson situational analysis to ensure adherence to the trial protocol.

Inclusion criteria

COOK stores are eligible if:







- They have at least 18 freezers that stock the Chef's wall ready-meals range.
- Vegetarian meals currently comprise over 20% of their Chef's wall ready meals as assessed by the COOK retail team.
- They can increase vegetarian facing in the Chef's wall range to 44-45%.

In addition to using the inclusion criteria, COOK selected intervention stores based on their geographical spread (1 store in the West Midlands and 4 stores in the Southeast) and the likelihood of store engagement in the trial.

Randomisation

Each of the 5 intervention stores will be randomised into the intervention. An external and blinded researcher will perform a simple, unconstrained random allocation, where all shops have an equal probability of being allocated to each position in the sequence. The stores will be randomised to start the intervention at the start of each week during the trial period, and the baseline data will be collected retrospectively after the trial starts. The intervention across the stores will be implemented in a step-wise manner (i.e. each week, a new store will start the intervention). This means that one store will run the intervention for 5 weeks, whereas others will run the intervention for either 4, 3, 2, or 1 week(s). The stores will be informed about the intervention implementation at least one month before it begins. Once the intervention begins, facings will be increased consistently across all stores on the same day at the start of each week. Figure 1 illustrates the stepped-wedge design for 5 COOK stores over six weeks.

Figure 1: This figure shows the implementation of the stepped-wedge design, with 5 stores as an example. Data from the pre-intervention and post-intervention periods will be used for exploratory analyses of time trends.

		Pre-	interv	ention	period		Inter	ventio	n (trial)	Post-i	Post-intervention period					
Week	s	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
	1															
s	2															
tore	3															
'es	4															
	5															

]: No intervention, data collection ongoing

: Intervention and data collection ongoing

Outcomes

Sales of all ready meals of the Chef's wall range will be obtained from electronic point of sales tills before, during and after the intervention period. We will collect details of the vegetarian product names, the units sold, their sales revenue (£), the ingredient list and the nutritional composition of the products stocked and sold during the intervention weeks. This data will be provided by all COOK stores running the intervention and matched non-intervention stores.

The primary and secondary outcomes are detailed in Table 1.



NUFFIELD DEPARTMENT OF **PRIMARY CARE** HEALTH SCIENCES Medical Sciences Division



Table 1: Primary and secondary outcomes for the COOK trial.

	Level	Outcome	Measurement	Rationale
1	Primary	The proportion of vegetarian ready-meal sales from the total sales of the Chef's wall.	Weekly sales data (units sold) of vegetarian ready meals out of total ready meal sales (meat-based and vegetarian)	To ensure we capture how many vegetarian ready-meals relative to meat-based ready-meals were sold by the increase in relative availability.
2	Secondary	Total sales (units sold and £) of all ready-meals (vegetarian and meat-based) of the Chef's wall and whole store.	Weekly sales data (£) of all ready meal sales (vegetarian and meat-based)	This will help us assess the effect of the intervention on total sales. Additionally, total sales information in the matched non-intervention stores will help us determine background trends in purchasing behaviours during the intervention period.
3	Secondary	Nutritional quality of all ready meal sales (vegetarian and meat-based)	Using the nutritional information provided by COOK to assess the nutritional quality (Kcal, total fat (unsaturated and saturated), sugar, fibre, protein carbohydrates, and salt) of ready-meals on Chefs wall.	To assess the nutritional quality of vegetarian and meat- based meals during the intervention vs control period, COOK may provide the nutritional information for all meals offered on the Chef's wall during the trial period.



NUFFIELD DEPARTMENT OF **PRIMARY CARE** HEALTH SCIENCES Medical Sciences Division



				Food system trials for healthier people and planet
4	Secondary	The nutritional profile of foods	The proportion of	To estimate the nutritional impact of products sold during
		purchased	products purchased	the intervention versus the control period and the relative
			that pass/fail the UK	change (from baseline to intervention) in the nutritional
			Nutrient Profile	impact of products sold.
			model (UK NPM, (22))	Whereas the previous analyses will assess each nutrient in isolation, this analysis will assess multiple nutrients to assess the overall nutritional profile of purchased foods. The UK NPM will be used as it is frequently used in policy contexts (e.g. (23)). The UK NPM scores foods based on the levels of nutrients to limit (Kcal, total sugars, saturated fat, sodium) and nutrients/components to encourage (fibre, protein, and fruit and vegetable content) present in a food. Foods are categorised as "Healthier" if they score less than 3 points.
5	Secondary	Environmental impact of all	The total	To estimate the environmental impact of products sold
	· · · · · · · · · · · · · · · · · · ·	ready meals on Chef's wall	environmental	during the intervention vs control period. Additionally, to
		during the intervention period	impact of meals sold	estimate the relative change (from baseline to intervention)
			will be estimated	in environmental impact of products.
			based on 4	
			environmental	
			indicators	
			(greenhouse gas	
			emissions, scarcity-	
1			weighted water	
1			stress, land use and	
1			eutrophication)	
			using an equivalent	







			method to that described by Clark et al. (24)	
6	Secondary	Health impact	Using the PRIMEtime model, the effect of increasing relative vegetarian meals availability will have on morbidity and mortality of the UK population will be assessed (2). Here, we will extrapolate results from the nutritional analysis of the trials under different scenarios of delivering the intervention at scale.	To estimate the potential impact on the health of the UK population of scaling up the intervention to be delivered in retailers throughout the UK.
7	Secondary	Economic evaluation	Measuring additional costs or savings in increasing the availability of vegetarian ready- meals, potential additional staff costs, and any revenue losses or	To assess the incremental cost of implementing the intervention, which measures the difference in cost between the intervention and control arms.







Statistical analyses

The trial protocol will be registered on the ISRCTN registry (<u>https://www.isrctn.com</u>).

Power calculations

Power calculations on the primary outcome were performed using an RShiny cluster randomised controlled trial power calculator (https://clusterrcts.shinyapps.io/rshinyapp/) based on published statistical theory (25, 26). Table 2 details the assumptions to achieve 88% power and an α = 0.05. Figure 2 illustrates that at a 0.05 significance level, the power is approximately 88% for a cluster size of 314 (in this instance, the cluster size refers to the number of sales from the Chef's Wall in a store during a study week. Our estimate is based on pilot analysis of COOK data).

Table 2. Inputs for power calculations

Trial designStepped-wedgeSampling structureCross-sectionalCorrelation structureTwo-period decay	
Sampling structure	
Correlation structure Two-period decay	
Plot set-up Cluster size vs power	
Allowance for varying cluster size Yes	
Coefficient of variation of cluster sizes 0.26	
Number of sequences 5	
Number of clusters per sequence	
Cluster size (per period) 314	
Within period intra-cluster correlation (ICC) 0.01284	
ICC lower extreme 0.0065	
ICC upper extreme 0.0192	
Cluster auto-correlation 0.488	
Outcome type Binary	
Outcome proportion under control 0.23	
Outcome proportion under intervention 0.32	





	Food system tri
Significance level	0.05
Normal approximation	T-distribution*

*A t-distribution was selected due to the need to correct for the small sample size.

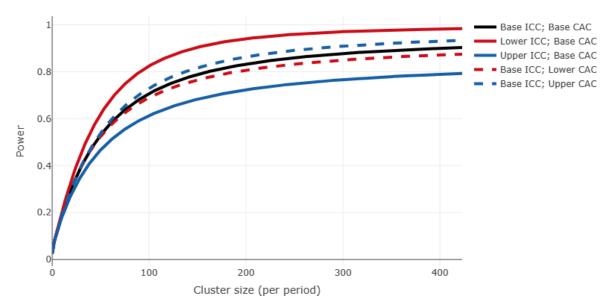


Figure 2. Cluster size vs. power curve

The curve shows the increase in power as the cluster-period sizes increase (for a fixed number of clusters). ICC: intra-cluster correlation, CAC: cluster auto-correlation

Analysis plan

The analysis aims to test the effect of increasing the relative availability of vegetarian ready meals on the proportion of vegetarian to meat sales.

1. Primary analysis

Mixed-effect hierarchical logistic regression models will be conducted. The units of analysis will be sales of ready meals selected from the Chef's Wall range. The outcome variable will be a binary variable indicating whether or not the meal is vegetarian. Sales will be nested in stores using random intercepts. A variable indicating whether the store-week is an intervention or control period will be the main predictor. This analysis will include only weeks 5-10 from the schedule shown in Figure 1. A fixed effect continuous time variable will be included in the model to account for possible secular trends in the outcome variable that could bias effect estimates.

2. Secondary analyses

A.) Analysing the effect of the intervention in secondary outcome measures





The same basic model structure described in the primary analysis section will be used for the following secondary outcome measures. However, models will be linear for continuous variables (a and b) and logistic for binary variables (c).

- a. environmental footprint per sale of all ready meal sales (GHG emissions, land use, water use, water pollution and biodiversity impact) options available and purchased.
- b. Nutritional quality per 100g of ready meal sales (kcal, protein, total fat (unsaturated and saturated), carbohydrates, sugar, fibre and salt, all measured per sold item)
- c. Proportion of products that pass the UK Nutrient Profile Model (i.e. has a UK NPM score of ≤ 3 if food, or ≤ 1 if drink)
- B.) Further non-hierarchical mixed effects linear regression models will be used for the following store-week level secondary outcome data:
 - a. weekly sales of total ready meals (in units sold)
 - b. weekly store sales revenue (£)

For these analyses, the unit of analysis will be store-weeks. A fixed effect continuous time variable will be included in the models.

Sensitivity analyses

A.) Per protocol analyses

This analysis will include only stores that adhered to the protocol during the situational analysis. A site will have adhered to the protocol if a) we receive usable photos for at least 80% of store weeks during the intervention period and b) the site visit confirms the percentage of facings shown in the photos for the weeks where we have site visits. This analysis will exclude store weeks where a) the photo shows that less than 40% of facings are vegetarian or b) the photo is unusable.

B.) Secular trends analyses

Using data from the matched non-intervention stores, we will explore whether there were nonlinear time trends in the primary and secondary outcome variables. To do this, we will construct models of the outcome variables predicted by a linear time variable or by a categorical study weeks variable. We will conduct a likelihood ratio test to detect whether the categorical variable is a better fit to the data, using p=0.05 as a threshold for decision-making. If we detect evidence of non-linear trends, we will conduct sensitivity analyses of the primary and secondary outcomes from the trial data, using fixed effects non-linear (e.g. polynomial) time variables.

C.) Different model structure to account for hierarchical structure of the dataset

We will explore model structures that account for clustering of the primary and secondary outcome variables. For example, we will explore models that allow for random slopes for the stores and for store-weeks to be nested in stores. Due to the risk of non-convergence, these structures have not been selected for the main analyses.



Data exclusions and missing data



The primary analysis will exclude store weeks where the weekly sales data (revenue and units sold) of vegetarian-ready meals are missing. The nutritional information of ready meals will be imputed if more than 10% of this data is missing.

Data Management

Access to data

Researchers listed in this protocol will have access to the research data. Access will be granted to the MS IDREC for the purposes of monitoring and/or audit of the research. SALIENT consortium members (Behavioural Insights Team, University of Cambridge, University of Warwick, University of Birmingham, University of Hertfordshire, University of Liverpool, the London School of Hygiene and Tropical Medicine, and Queen Mary University of London) may also request to access this data under an existing collaboration agreement (available on request).

Data sharing

We will draft and share a data-sharing agreement with COOK before the trial begins. Appendix 1 details the data we have requested from COOK. Data will be shared securely using Nexus365 OneDrive for Business. If OneDrive for Business is unsuitable or unavailable, we will contact the Medical Science Division (MSD) IT department for advice on alternative platforms.

Data handling and record keeping

Data collected throughout the study will be kept on password-protected university network drives. Research data and records from this study will be kept on secure university network drives for five years before being deleted.

Trial monitoring

Baseline monitoring

Before the intervention begins, we will collect photos of freezer layouts and facings of the Chef's wall in intervention stores. The store staff will share these pictures. Additionally, the trial team will contact the store managers to discuss the practical delivery of the intervention and address any queries or concerns they may have.

Situational analysis

During the 6-week intervention period, the trial team will ask the store managers/staff for weekly pictures of products, freezer layouts, and facings on the Chef's wall in the intervention stores. This is to ensure that the intervention is being implemented per protocol. Additionally, we will conduct inperson situational analysis at least once during the data collection period in intervention stores. Precisely, we will monitor:

• Whether the proportion of vegetarian meals has been increased as detailed in the protocol.





- Whether any events have affected data collection, i.e., till malfunctions, freezer malfunctions.
- Whether any promotions are running simultaneously during the intervention period.

Process evaluation

The process evaluation plan is being developed jointly with the London School of Hygiene and Tropical Medicine and will form a separate ethics submission. The process evaluation will assess the quality of implementation of the intervention as well as the barriers to and facilitators of implementation.

Process evaluation will take the following form:

- Semi-structured interviews with store managers and customer-facing staff. These staff will be asked to give their perspectives on the anticipated effectiveness of the trial, barriers they met during the intervention and their views on the increased provision of vegetarian meals. Interviews will take place after the intervention period.
- Interviews with key decision makers at COOK, particularly the head of sustainability, finance and chef(s) (food production). From their point of view, we would like to know about the implementation process, the costs involved in running the intervention, and whether there were any unintended consequences (e.g. additional food waste). We will also ask their views on anticipated trial effectiveness. Interviews will take place after the intervention period.
- Interviews with customers: Store staff will introduce the intervention to customers at the checkout and provide a leaflet explaining the process evaluation. This way, the customers can contact the team conducting the process evaluation and be interviewed about their experiences during the intervention.

All interviews will be audio-recorded, subject to participant consent.

Economic evaluation and modelling

The trial team will assess the incremental cost of implementing the intervention, which measures the difference in cost between the intervention and control arms. This includes additional costs or savings of increasing the availability of vegetarian ready-meals, potential additional staff costs, and any revenue losses or gains resulting from implementing the intervention. These costs will then be offset against any change in outcomes to form an economic evaluation.

Additionally, utilising the PRIMEtime model (19), the impact of increasing the relative availability of vegetarian meals on the morbidity and mortality rates of the UK population will be evaluated and modelled into health outcomes such as Quality-Adjusted Life Years (QALYs). Through this process, we will extrapolate the primary and secondary outcomes observed in the trial to understand the possible impacts of scaling up the intervention for implementation in retail settings across the UK. The PRIMEtime model is a proportional multistate life table model that represents the current population of the UK. This population is projected forward in time following incidence and fatality rates for diet-related cardiovascular disease and cancers. In scenario analyses, distributions of the nutritional quality of the population are estimated assuming the trial results are delivered at scales. These distributions are used to calculate Population Impact Fractions, which estimate the change in incidence and fatality rates for our scenarios. The difference between the scenario and baseline





model runs are used to estimate the potential impact of the intervention on mortality and morbidity. Lastly, a cost-effectiveness analysis will then be conducted by comparing the incremental cost and outcome between the control and intervention arms to determine the cost-effectiveness of the intervention i.e., cost per Quality-Adjusted Life Year (QALY) gained.

Ethical approval

Ethical approval will be sought from the Central University Research Ethics Committee at the University of Oxford. The research protocol and any proposed materials for advertisement will be sent to the ethical committee for approval. All substantial amendments to the original approved documents will be sent to the above parties by the investigator, and approval will be gained where necessary.

The process evaluation is led by the London School of Hygiene and Tropical Medicine (LSHTM) and was subject to a separate ethics application (LSHTM ref: 29553 /RR/33206, approved on 19 December 2023).





Proposed timeline

TIMELINE	0 '23	Ν	D	J '24	F	Μ	Α	М	J	J	Α	S	0	Ν	D	J '25	F	Μ	A	М
Meet with the COOK intervention team																				
Share protocol with the Oxford team																				
Share updated protocol with the SALIENT team																				
Ethics application																				
Data sharing agreements/resources																				
Register protocol																				
Prepare trial materials/resources																				
Trial period																				
Situational analysis																				
Process Evaluation																				
Data analysis																			<u> </u>	<u> </u>
Write up results and submit for publication																				





Dissemination opportunities

The SALIENT consortium is committed to disseminating trial findings to key actors working to improve the food system.

The consortium's communication strategy will use a mix of communication approaches. Depending on the audience and the insights from the trial, we might use the following dissemination approaches:

- Academic publications: We will publish paper(s) in peer-reviewed academic journals.
- **Presentations at conferences**: We might present trial findings at academic conferences and might present at other relevant events.
- Direct communication with policymakers: The consortium will communicate key trial insights (process, outcomes, learnings) with the project Programme Board directly. The Programme Board includes members from the following Government Departments: Department of Food, Environment and Rural Affairs; Food Standards Agency; Cabinet Office; HM Treasury; Department of Health and Social Care; Department for Levelling Up, Housing and Communities; Department for Education.
- **Content production**: To reach a wider policy audience, we might produce policy briefs to accompany academic journal outputs.
- **Digital and social media communication**: We might publish content on our social channels (website, social media platforms, newsletters).
- Media press releases: We might look to reach wider audiences by publishing press releases.

REFERENCES

1. Brown CA, Lilford RJ. The stepped wedge trial design: a systematic review. BMC Med Res Methodol. 2006;6:54.

2. Briggs ADM, Cobiac LJ, Wolstenholme J, Scarborough P. PRIMEtime CE: a multistate life table model for estimating the cost-effectiveness of interventions affecting diet and physical activity. BMC Health Services Research. 2019;19(1):485.

3. Team RC. The R Project for Statistical Computing Vienna, Austria 2023 [Available from: <u>https://www.r-project.org/</u>.

4. Everest G, Marshall L, Fraser C, Briggs A. Addressing the leading risk factors for ill health: a review of government policies tackling smoking, poor diet, physical inactivity and harmful alcohol use in England.: The Health Foundation; 2022.

5. Knuppel A, Papier K, Fensom GK, Appleby PN, Schmidt JA, Tong TYN, et al. Meat intake and cancer risk: prospective analyses in UK Biobank. International Journal of Epidemiology. 2020;49(5):1540-52.

6. Papier K, Fensom GK, Knuppel A, Appleby PN, Tong TYN, Schmidt JA, et al. Meat consumption and risk of 25 common conditions: outcome-wide analyses in 475,000 men and women in the UK Biobank study. BMC Medicine. 2021;19(1):53.

7. Benton T, Bieg. C, Harwatt. H, Pudasaini. R, Wellesley. L. Food system impacts on biodiversity loss. Three levers for food system transformation in support of nature. Chatham House; 2021 3 February 2021.







8. Dalin C, Outhwaite CL. Impacts of Global Food Systems on Biodiversity and Water: The Vision of Two Reports and Future Aims. One Earth. 2019;1(3):298-302.

Crippa M, Solazzo E, Guizzardi D, Monforti-Ferrario F, Tubiello FN, Leip A. Food systems are responsible for a third of global anthropogenic GHG emissions. Nature Food. 2021;2(3):198-209.
 Xu X, Sharma P, Shu S, Lin T-S, Ciais P, Tubiello FN, et al. Global greenhouse gas emissions

from animal-based foods are twice those of plant-based foods. Nature Food. 2021;2(9):724-32.

11. Audsley E, Brander M, Chatterton J, Murphy-Bokern D, Webster C, Williams A. How long can we go? An assessment of greenhouse gas emissions from the UK food system and the scope for reduction by 2050. WWF-UK; 2009.

12. Dimbleby H. National Food Strategy: part two. 2021.

13. Marteau TM, Ogilvie D, Roland M, Suhrcke M, Kelly MP. Judging nudging: can nudging improve population health? BMJ. 2011;342:d228.

14. Hollands GJ, Carter P, Anwer S, King SE, Jebb SA, Ogilvie D, et al. Altering the availability or proximity of food, alcohol, and tobacco products to change their selection and consumption. Cochrane Database Syst Rev. 2019;9(9):Cd012573.

15. Roe LS, Meengs JS, Birch LL, Rolls BJ. Serving a variety of vegetables and fruit as a snack increased intake in preschool children123. The American Journal of Clinical Nutrition. 2013;98(3):693-9.

16. Pechey R, Cartwright E, Pilling M, Hollands GJ, Vasiljevic M, Jebb SA, et al. Impact of increasing the proportion of healthier foods available on energy purchased in worksite cafeterias: A stepped wedge randomized controlled pilot trial. Appetite. 2019;133:286-96.

17. Kocken PL, Eeuwijk J, Van Kesteren NM, Dusseldorp E, Buijs G, Bassa-Dafesh Z, et al. Promoting the purchase of low-calorie foods from school vending machines: a cluster-randomized controlled study. J Sch Health. 2012;82(3):115-22.

18. Garnett EE, Balmford A, Sandbrook C, Pilling MA, Marteau TM. Impact of increasing vegetarian availability on meal selection and sales in cafeterias. Proc Natl Acad Sci U S A. 2019;116(42):20923-9.

19. Pechey R, Bateman P, Cook B, Jebb SA. Impact of increasing the relative availability of meatfree options on food selection: two natural field experiments and an online randomised trial. International Journal of Behavioral Nutrition and Physical Activity. 2022;19(1):9.

20. Trewern J, Chenoweth J, Christie I, Halevy S. Does promoting plant-based products in Veganuary lead to increased sales, and a reduction in meat sales? A natural experiment in a supermarket setting. Public Health Nutrition. 2022;25(11):3204-14.

21. McPhedran R, Zhuo S, Zamperetti L, Gold N. The effects of Veganuary on meal choices in workplace cafeterias: an interrupted time series analysis. Behavioural Public Policy. 2023:1-20.

22. Health Do. Nutrient Profiling Technical Guidance 2011 1 January.

23. Care DoHaS. Restricting promotions of products high in fat, sugar or salt by location and by volume price: implementation guidance 2023 [Available from:

https://www.gov.uk/government/publications/restricting-promotions-of-products-high-in-fat-sugaror-salt-by-location-and-by-volume-price/restricting-promotions-of-products-high-in-fat-sugar-orsalt-by-location-and-by-volume-price-implementation-guidance.

24. Clark M, Springmann M, Rayner M, Scarborough P, Hill J, Tilman D, et al. Estimating the environmental impacts of 57,000 food products. Proc Natl Acad Sci U S A. 2022;119(33):e2120584119.

25. Hooper R, Bourke L. Cluster randomised trials with repeated cross sections: alternatives to parallel group designs. Bmj. 2015;350:h2925.

26. Hooper R, Teerenstra S, de Hoop E, Eldridge S. Sample size calculation for stepped wedge and other longitudinal cluster randomised trials. Stat Med. 2016;35(26):4718-28.





APPENDIX 1 COOK_data template (1).xlsx - Google Sheets