

## STATISTICAL ANALYSIS PLAN

Working title	<b>The effect of a relative availability intervention on the sale of a frozen ready-meal retailer.</b>
Date of plan	12 August 2024

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 study, "vegetarian" will be used to refer to both vegetarian and vegan meals.
Stepped wedge randomised controlled trial	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).

R	Software program used for statistical analyses (3).
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### Background to the study and analysis

Dietary choices play a crucial role in individual health and environmental sustainability, as certain diets have higher environmental impacts than others and contribute to ill health. Food selection can be influenced by changing food environments (e.g., cafeterias and food retailers). Some experiments conducted in university and worksite canteens suggest that increasing the availability of vegetarian options can boost their sales (4, 5). However, research in real-world retail settings is limited. We will conduct a stepped wedge randomised controlled trial to increase the relative availability of vegetarian meal facings and measure the effect of the intervention on total meal sales in a frozen ready meal retailer called COOK. Furthermore, we will conduct a process evaluation of the intervention to understand how the intervention was implemented and its acceptability in a real-world setting and identify what improvements could be made in the future. Finally, 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.

Aim	To determine the impact of increased facings of vegetarian ready-meals on the proportion of vegetarian ready-meal unit sales and total ready-meal sales.
Specific hypothesis under study	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.
Primary Outcome	The proportion of vegetarian ready-meal unit sales from the total sales of the Chef's wall.
Secondary outcomes	<ul style="list-style-type: none"> <li>• Total sales (units sold and £) of all ready meals (vegetarian and meat-based) of the Chef's wall and whole store.</li> <li>• Nutritional quality of all ready meal sales (vegetarian and meat-based)</li> <li>• The nutritional profile of foods purchased</li> <li>• Environmental impact of all ready meals on Chef's wall during the intervention period</li> <li>• Health impact of increasing vegetarian ready meals on the wider UK population</li> <li>• The cost-effectiveness of the intervention</li> </ul>

### Data details

Study type	Stepped wedge randomised controlled trial
Dataset used	Sales and product data of the store
Analysis package	R studio

Study population	5 stores (owned by COOK company)
Duration	6 weeks (intervention will be rolled out in a step-wise manner over 6 weeks).  We will also collect sales data for the pre-intervention (4 weeks ) and post-intervention (4 weeks) periods.
Inclusion criteria	<ul style="list-style-type: none"> <li>• Stores with at least 18 freezers that stock the Chef's wall ready-meals range.</li> <li>• Stores where vegetarian meals currently comprise over 20% of their Chef's wall ready-meals as assessed by the COOK retail team.</li> <li>• Stores that can increase vegetarian facing in the Chef's wall range to 44-45%.</li> </ul> <p>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.</p>
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.

Outcome measures	
Primary outcome measures	Sales data (units sold) of vegetarian ready meals out of total ready meals sales (i.e. meat-based and vegetarian) will be collected pre-intervention (four weeks), during the intervention period (six weeks) and post-intervention (four weeks). Sales data will be obtained from electronic point-of-sale tills.
Secondary outcome measures	<p>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 before, during, and after the intervention. These data will be used for secondary analyses assessing the longer-term time trends in the outcome measures. Specifically:</p> <ol style="list-style-type: none"> <li>1. Sales data (units sold and £ revenue) of all ready meals (vegetarian and meat-based).</li> <li>2. The nutritional quality of ready meals will be measured using nutritional information provided by the retailer on the following nutrients: Kcal, total fat (unsaturated and saturated), sugar, fibre, protein, carbohydrates, and salt.</li> <li>3. The nutritional profile of foods purchased will be measured by analysing the proportion of products purchased that pass or fail the UK Nutrient Profile Model (UK NPM)(6).</li> <li>4. The environmental impact of meals sold will be estimated by calculating four environmental indicators (greenhouse gas emissions, scarcity-weighted water stress, land use and eutrophication) using a method established by Clark et al. (7).</li> </ol>

	<ol style="list-style-type: none"> <li>5. The health impact of increasing relative vegetarian meal availability on the morbidity and mortality of the UK population will be assessed using an established proportional multistate life table model, the PRIMETIME model.</li> <li>6. The cost-effectiveness analysis will be conducted by analysing the additional costs and/or savings and any revenue losses or gains associated with increasing the availability of vegetarian meals.</li> </ol>
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### Proposed analytical strategy

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  $\leq 3$  if food, or  $\leq 1$  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 non-linear 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.

### References

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