Protocol

Supporting Companies to Reform Nutrition Policies and Practices (REFORM): A Multi-centre Cluster Randomised Controlled Trial

This Project aims to assess the effects of the provision of tailored support to food companies to reform their nutrition-related policies and practices

Principal Investigators

Professor Cliona Ni Mhurchu
National Institute for Health Innovation
The University of Auckland
New Zealand

Associate Professor Gary Sacks
Global Obesity Centre
Deakin University
Australia

Study Co-ordinating Centres

Postal address
National Institute for Health Innovation
School of Population Health
The University of Auckland
Private Bag 92019
Auckland Mail Centre
Auckland 1142
New Zealand

Tel: +64 9 923 4764
Email: reform@auckland.ac.nz

Street address
National Institute for Health Innovation
The University of Auckland
Building 507
Grafton Campus
22-30 Park Avenue, Grafton
Auckland 1023
New Zealand

Global Obesity Centre
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia

Tel: +61 3 9251 7105
Email: gary.sacks@deakin.edu.au

Global Obesity Centre
Institute for Health Transformation
Deakin University
221 Burwood Highway
Burwood VIC 3125
Australia

Steering Group Committee Members

Professor Cliona Ni Mhurchu
Principal Investigator, New Zealand

National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Tel: +64 9 923 4494
Emergency no: +64 21 21 722240
Email: c.nimhurchu@auckland.ac.nz

Associate Professor Gary Sacks
Principal Investigator, Australia

Global Obesity Centre
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: +61 3 9251 7105
Emergency no: +61 403 491 205
Email: gary.sacks@deakin.edu.au

Associate Professor Adrian Cameron
Co-investigator

Global Obesity Centre
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: +61 3 9251 7741
Emergency no: +61 402 086 294
Email: adrian.cameron@deakin.edu.au

Professor Bruce Neal
Co-investigator

The George Institute for Global Health
Level 5, 1 King St
Newtown NSW 2042
Australia
Tel: +61 2 80524300
Emergency no: +61 408 481 475
Email: bneal@georgeinstitute.org.au

Dr Helen Eyles
Co-investigator

National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Tel: +64 9 923 4658
Emergency no: +64 21 224 3536
Email: h.eyles@auckland.ac.nz

Dr Kathryn Backholer
Co-investigator

Global Obesity Centre
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: +61 3 92443836
Emergency no: +61 414 290 481
Email: kathryn.backholer@deakin.edu.au

Professor Anna Peeters
Co-investigator

Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: +61 3 92445423
Emergency no: +61 400 612 427
Email: anna.peeters@deakin.edu.au

Dr Yannan Jiang
Co-investigator

National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Tel: +64 9 923 4725
Emergency no: +64 21 209 7967
Email: y.jiang@auckland.ac.nz

Ms Jaithri Ananthapavan
Co-investigator

Deakin Health Economics
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: +61 3 92517181
Emergency no: +61 488 033 633
Email: jaithri.ananthapavan@deakin.edu.au

Professor Boyd Swinburn
Associate investigator

Department of Epidemiology & Biostatistics
University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Tel: +64 9 923 9135
Emergency no: +64 22 1679636
Email: boyd.swinburn@auckland.ac.nz

Dr Helen Trevena
Associate investigator

Helen Trevena
Menzies Centre for Health Policy
Sydney School of Public Health
The University of Sydney
Charles Perkins Centre D17
The University of Sydney NSW 2006
Tel: +61 2 8627 6398
Email: helen.trevena@sydney.edu.au

Ms Jane Martin
Associate investigator

Obesity Policy Coalition
615 St Kilda Rd
Melbourne VIC 3000, Australia
Auckland 1142, New Zealand
Tel: +61 3 9514 6456
Email: jane.martin@cancervic.org.au

Dr Miranda Blake
Associate investigator

Global Obesity Centre
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: +61 3 92468487
Email: miranda.blake@deakin.edu.au

Study Management Committee Members

Professor Cliona Ni Mhurchu
Principal Investigator, New Zealand

National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Tel: 64 9 923 4494
Emergency no: +64 21 21 722240
Email: c.nimhurchu@auckland.ac.nz

Associate Professor Gary Sacks
Principal Investigator, Australia

Global Obesity Centre
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: +61 3 9251 7105
Emergency no: +61 403 491 205
Email: gary.sacks@deakin.edu.au

Ms Elaine Umali
Project Manager, New Zealand

National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Tel: +64 9 923 9095

Emergency no: +64 27 5765108
Email: e.umali@auckland.ac.nz
PM from 7th Feb 2024

Mrs Jacqui Grey
Project Manager, New Zealand

National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Email: e.umali@auckland.ac.nz
PM from 15th June 2021 until 18th Jan 2024

Ms Sally Schultz
Project Manager, Australia

Global Obesity Centre
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: 61 3 9244 5455
Emergency no: +61 434 363 784
Email: sally.schultz@deakin.edu.au

Ms Jasmine Chan
Project Manager, Australia

Global Obesity Centre
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: 61 3 9244 6235
Emergency no: +61 415 232 789
Email: jasmine.chan@deakin.edu.au
PM from 15th March 2021

Ms Josephine Marshall
Dietitian/ Research Fellow

Global Obesity Centre
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: 61 3 9244 6235
Emergency no: +61 415 232 789
Email: josephine.marshall@deakin.edu.au

Ms Rhodi Bulloch
Research Fellow

National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Tel: +64 27 363 0548
Emergency no: +64 27 363 0548
Email: r.bulloch@auckland.ac.nz

Research Fellow until 8th October 2021

Ms Stephanie Shen
Research Assistant

National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Email: stephanie.shen@auckland.ac.nz
Research Assistant from 6th December 2021 until 11th November 2022

Ms Caitlin Haliburton
Research Assistant

National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Email: caitlin.haliburton@auckland.ac.nz
Research Assistant from 10th December 2022

Dr Yannan Jiang
Biostatistician

University of Auckland
Private Bag 92019
Auckland 1142, New Zealand
Tel: +64 9 923 4725
Emergency no: +64 21 209 7967
Email: y.jiang@auckland.ac.nz

Ms Jaithri Ananthapavan
Economist

Deakin Health Economics
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: +61 3 92517181
Emergency no: +61 488 033 633
Email: jaithri.ananthapavan@deakin.edu.au

Dr Miranda Blake
Process evaluation

Global Obesity Centre
Institute for Health Transformation
Deakin University
Locked Bag 20000
Geelong VIC 3220
Australia
Tel: +61 3 92468487
Email: miranda.blake@deakin.edu.au

Project Funders

The funder of the New Zealand trial is the Health Research Council (HRC) of New Zealand [Programme Grant Number: 18/672]. Dr Helen Eyles is supported by a Heart Foundation Senior Fellowship from the Heart Foundation of New Zealand. The design, conduct, analyses, and interpretation of trial results will all be independent of the funders.

The joint funders of the Australian trial are the National Health & Medical Research Council (NHMRC), the Victorian Health Promotion Foundation (VicHealth), and the Australian Government Department of Health (DoH). A/Profs Gary Sacks, Adrian Cameron and Kathryn Backholer are supported by Heart Foundation Future Leader Fellowships from the National Heart Foundation of Australia. The design, conduct, analyses, and interpretation of trial results will all be independent of the funders.

Signature Page

Author(s):

Principal Investigator, New Zealand Prof Cliona Ni Mhurchu	**Signature:**	**Date:** 12 April 2021
Principal Investigator, Australia Assoc Prof Gary Sacks	**Signature:**	**Date:** 12 April 2021
NIHI Signatory: Director Prof Chris Bullen	**Signature:**	**Date:** 12 April 2021
Deakin IHT Signatory: Director Prof Anna Peeters	**Signature:**	**Date:** 14/5/2021

Revision Chronology:	Date	Type *e.g., Original, Administrative*

Table of contents

1. Overview

Title of study: Supporting Companies to Reform Nutrition Policies and Practices (REFORM)

Investigators and study centres
This study has been designed by independent investigators at the National Institute for Health Innovation (NIHI), University of Auckland, New Zealand, the Global Obesity Centre (GLOBE), Institute for Health Transformation (IHT), Deakin University, Australia, and The George Institute for Global Health (TGI), Australia. The overall design and conduct of this trial are the responsibility of the Principal Investigators and members of the Study Management Committee. The study will be co-ordinated jointly by NIHI and GLOBE.

Study period: July 2020 – June 2024

Objectives: The primary objective of this trial is to determine the effects on the nutrient profile (Health Star Rating) of food company product portfolios, of the provision of tailored support to companies on their nutrition-related policies and practices (food composition, nutrition labelling, marketing to children, food accessibility), compared to food companies that are not offered the programme (the control).

Duration of intervention: 12 months

Study design and methodology: The REFORM study is a parallel, two-arm, cluster randomised controlled trial. Food companies serving as the clusters will be randomly assigned (2:1 ratio) to receive either a tailored support intervention programme or no intervention. Randomisation will be stratified by country (Australia, New Zealand), industry sector (chained consumer food services, other packaged food/non-alcoholic beverage companies), and company size (greater than or equal to median category revenue, less than median category revenue). All companies will be followed for 24 months, with outcome assessments at baseline, 12 months, and 24 months.

Study population: Eligible companies will have Australia- and/or New Zealand-based production operations of foods or non-alcoholic beverages, and a product portfolio of at least 10 products where reformulation is considered by the research team to be feasible. Companies will be identified using the Euromonitor Passport database and cross-checked against the Australian FoodSwitch and New Zealand Nutritrack databases, to ensure annually updated food composition and labelling data are available for identified companies.

Sample size: A total of 150 food companies (intervention n=100, control n=50) across both countries.

Main criteria for inclusion
- A company involved in the production of food and/or non-alcoholic beverages
- >$10 million in annual retail sales revenue
- Holding Company or Head Office and manufacturing located in Australia or New Zealand
- Product portfolio of at least 10 products considered amenable to reformulation

Exclusion criteria
Companies will be excluded if:
- They manufacture chewing gum products, sports supplements, or infant formula ***only***
- They are currently engaged with the research team on similar interventions
- They are supermarkets or retailers/distributors/importers/wholesalers only
- Their product nutrition information is not available in the Nutritrack, or FoodSwitch databases and therefore nutritional profile and HSR is unable to be assessed.

Criteria for evaluation
Primary outcome
The primary outcome will be the nutrient profile (measured using the Health Star Rating (HSR) system) of the foods and beverages produced by the food companies at 24 months post-baseline.

Secondary outcomes that will be measured are:
- Nutrient profile (measured using the HSR system) of the foods and beverages produced by the food companies at 12 months post-baseline
- Nutrient content (including sodium, sugar, and saturated fat) of the foods and beverages produced by the food companies at 12- and 24 months post-baseline
- Display of HSR labels on packaged foods and beverages produced by the food companies at 24 months post-baseline
- Company nutrition-related policies and commitments at 24 months post-baseline, measured using the validated Business Impact Assessment-Obesity and population nutrition (BIA-Obesity) tool
- Company engagement with the intervention and reported enablers and barriers to change
- Cost-effectiveness of the intervention and modelled impact on population health

Statistical methods
Study power
A total of 150 companies (intervention n=100, control n=50) across both countries, with a minimum of 10 products per company, will provide 90% power at a 5% level of significance to detect a minimum 0.48-unit difference between groups in the mean HSR of all packaged food products over the 24-month follow-up period, assuming a mean HSR of products of 2.95, a standard deviation (SD) of 1.25, and an intra-cluster correlation (ICC) between products produced by the same company of 0.4. This would constitute an approximate 16% increase in the star rating (healthiness) of foods produced by the intervention companies compared to foods produced by the control group companies.

We estimate that about half of the intervention companies will participate in the intervention programme, which will reduce the effective sample size. A total of 100 companies (50 intervention and 50 control companies) will provide 80% power to detect the expected effect size on the primary outcome under the same assumptions.

Statistical analysis
Trial analyses will be conducted on an intention-to-treat (ITT) basis, following the CONSORT 2010 statement guidance with extension to cluster randomised trials. All randomised companies will be included in the primary ITT analysis. A per-protocol (PP)

analysis will also be conducted including only those intervention companies that participate in the intervention programme as per protocol.

Descriptive information will be presented at both company and food category level by treatment group pre- and post-intervention. Primary and secondary efficacy outcomes will be tested between intervention and control groups using generalised linear mixed models. The fixed effects will include treatment group, stratification factors, baseline outcome value and key food categories. Food company will be included as a random cluster effect. The ICC coefficients will be estimated using the trial data. The size of any intervention effect will be estimated overall and by key food categories. Country-level analysis will also be undertaken.

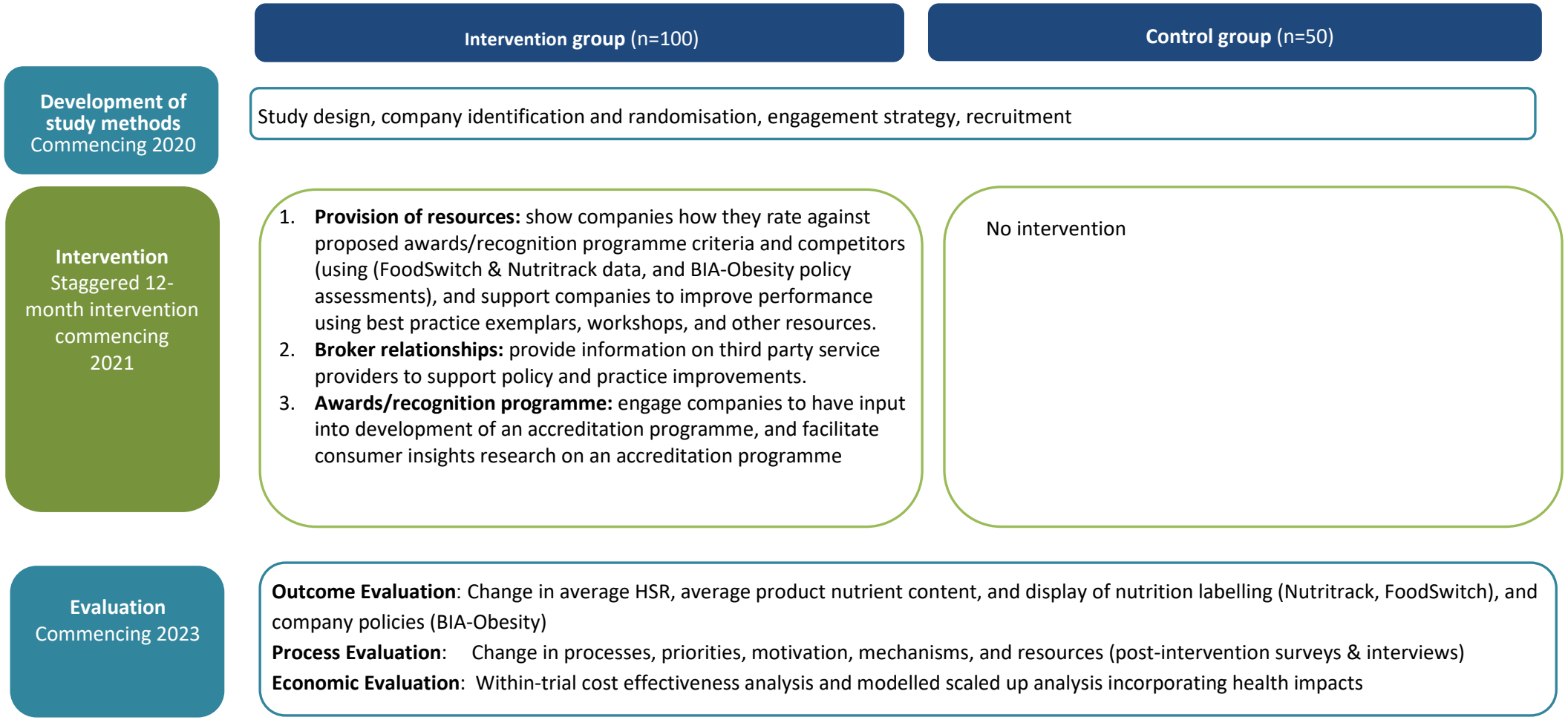
The extent to which companies engage with the intervention and the ways in which intervention activities influence company activities will be assessed via a comprehensive process evaluation, guided by theoretically and evidence-based programme logic of intervention pathways of effect and outcomes. The process evaluation will use a convergent mixed methods approach using pre-post surveys and post-intervention semi-structured interviews with company representatives to examine changes in company prioritisation, motivation, mechanisms, and resources for making nutrition-related policy and practice changes.

If the intervention is successful in changing the primary outcome, an economic evaluation will be conducted to assess its cost-effectiveness (cost per change in HSR). The longer-term population health impact of changes in HSR (cost per Health-Adjusted Life Year gained) will also be modelled. If the intervention is not successful, a costing analysis will be undertaken instead. All economic outputs will be reported with 95% uncertainty intervals, and selected scenario and sensitivity analyses will be undertaken to test the impact of important assumptions (including intervention reach and industry costs) on cost-effectiveness results.

Funding

This project is funded by the Health Research Council of New Zealand, the Australian National Health & Medical Research Council, the Victorian Health Promotion Foundation (VicHealth) and the Australian Government Department of Health (DoH).

2. Study Plan Schematic



3. Background

3.1 Burden of diet-related disease

Unhealthy diets and excess body weight are leading contributors to poor health in Australia and New Zealand (NZ) (1, 2). Less than 7% of Australians consume diets that are consistent with the Australian Dietary Guidelines, and at least 35% of the energy intake of adults and up to 41% of the energy intake of children comes from 'less healthy' food and drinks (3). Two in three Australian adults and one in four children are overweight or obese (4). In NZ, the prevalence of overweight and obesity is similar in adults (65%) but higher in children (31%) (5). The high prevalence of obesity and diet-related disease has a high cost to the economy, including large impacts on the health care system and productivity (6).

3.2 Drivers of unhealthy diets and obesity

Unhealthy food environments are the major drivers of obesity and related non-communicable diseases (NCDs) (7). In Australia and NZ, as in most high- and middle-income countries, food environments are dominated by highly accessible, relatively cheap, and heavily promoted processed foods that typically contain high levels of sodium, saturated fat and/or added sugar (7, 8). In both Australia and NZ, less than half the packaged food available in supermarkets is classified as healthy, (8-10) and ~75% of Australian dietary sodium comes from processed foods (11).

3.3 Policy response in Australia and New Zealand

Improving the healthiness of food environments requires a comprehensive societal response, including government policies and wide-scale action from the food industry (12, 13). In Australia and NZ, current government policy in this area relies heavily on voluntary company actions through flagship initiatives such as the HSR nutrition labelling scheme and the Australian Healthy Food Partnership (a collaboration between government, food companies, and community groups, with the current focus mainly on product reformulation) (14). Some food and beverage manufacturers and retailers have taken positive steps to address population nutrition and obesity-related issues through changes to product development, reducing promotion of 'less healthy' food to children, and improved nutrition labelling (15, 16). Despite this, our recent assessments of company policies and commitments related to nutrition found they are frequently non-specific and limited in scope, and the overall response from the food industry to date has been weak and insufficient to meaningfully address population nutrition issues in Australia and NZ (15, 16). These findings are consistent with evidence from other countries (such as in relation to the United Kingdom government's Public Health Responsibility Deal) where voluntary action (and support for industry) has been limited and compliance with voluntary pledges has been poor (17).

While the Australian and NZ governments encourage food companies to support healthy food environments via their voluntary schemes, and some food companies have expressly stated their willingness to act (15, 16), there is currently very limited support and expertise in place to guide companies in their policy development and implementation. In Australia, organisations such as VicHealth and the Heart Foundation provide some support for product reformulation (with a current focus on sodium reduction), with these types of initiatives having proved generally successful in Australia and elsewhere in relation to their specific policy targets (18, 19). State governments in Australia also offer some support for food companies to provide healthier products, such as through the Victorian Department of Health and Human Services' Healthy

Eating Advisory Service (HEAS) (20). However, these schemes are limited in their scope (currently focused mainly on guidance with assessment of the healthiness of products), their level of assistance available, and do not apply nationally. The level of support for food companies is similarly low in NZ with only the Heart Foundation offering assistance to the food industry to improve the nutritional quality of foods (21).

4. Rationale for the Present Study

In a recent project led by A/Prof Sacks, we developed the novel BIA-Obesity (Business Impact Assessment – Obesity and population nutrition) tool and process for assessing food company policies and practices related to nutrition (22). The BIA-Obesity tool assesses key domains related to obesity prevention and improving population nutrition, including: i) overall corporate strategy related to nutrition; ii) product composition (reformulation of existing products and new product development); iii) product and brand promotion; iv) nutrition labelling; and v) product accessibility (including availability and affordability). BIA-Obesity involves extensive engagement with company representatives as part of the assessment process. The BIA-Obesity monitoring tool has now been applied in Australia (2018), NZ (2018), Canada (2019) and Malaysia (2019), with assessment underway in parts of Europe as part of the INFORMAS (International Network for Food and Obesity/Non-communicable Diseases Research, Monitoring and Action Support) initiative (23). Levels of company engagement with the BIA-Obesity initiative in Australia, NZ and Canada were high, with the majority of the included companies actively engaging in the process (22). Our evaluation of the BIA-Obesity initiative in Australia revealed that company representatives found the process extremely useful in generating internal advocacy for action, and in highlighting priority focus areas at the executive-level (24). In addition, the evaluation of BIA-Obesity indicated that companies are calling for expert support to design and implement best practice policies related to nutrition. For example, company representatives that participated in BIA-Obesity stated:

> *"When we want [nutrition-related] advice and different insights it's very, very hard to get. It's really hard to get because sometimes the best perspective to help you think about what you're doing is a completely different perspective to the one [the company has]... A willingness [from the public health community] to provide input and advice… would be really helpful"* – Company representative (external/public relations/affairs role)

> "*What would be interesting for you [public health researchers], I think, would be to go directly to some of the food companies at the bottom of the list [of food companies ranked by their nutrition-related policies] who don't have the nutrition resources... maybe your role in some of those lower ranking companies is distinctly to generate action to improve their policies and practices*" – Company representative

Moreover, in the last 18 months we have been approached by a range of food manufacturers (including Fonterra, Nestlé and Lion), supermarkets (including all major chains), and small retailers to provide our expertise regarding their nutrition policies on a consultancy basis. However, there is currently no evidence that such a model is effective. In addition, providing support to companies through consultancy would breach the conflict of interest guidelines of the Global Obesity Centre (GLOBE) at Deakin University (25). With an RCT funded from government sources, we can avoid financial conflict of interest and generate rigorous evidence of whether the process of offering expert advice and support can strengthen voluntary initiatives and have a meaningful impact from a population health perspective.

Advocacy is the process of influencing people and organisations to create change (26). Coupled with direct support for change, advocacy can potentially lead to improvements in corporate behaviours and industry practices that are currently misaligned with health (27). Our experience strongly suggests that many large corporations in the food industry are keen to shift their practices towards healthier policies and products, particularly in response to consumer opinion and a desire to maintain brand reputation. However, little evidence exists to describe the effects of advocacy and support programmes on food company behaviour (28).

Members of the project team, including Prof Neal and Dr Trevena, previously conducted a pilot advocacy intervention to reduce the sodium content of processed foods in Australia (2013-2015) (29). Twenty-three companies in the control group received no specific intervention and 22 companies in the intervention group received an advocacy programme based on an established theory of change model (COM-B) (30). Evaluation of the pilot programme identified no differences between the intervention and control groups in pre-defined interim measures, although the study had power to detect only large effects on food composition measures (29). Further, the primary outcome was the sodium content of foods, when a composite measure of overall nutrient profile is arguably a more appropriate measure for a food reformulation initiative. This pilot work provided important insights into mechanisms for delivering an effective advocacy intervention involving food companies as well as the level of resources and time required. The learnings from the pilot study have directly informed the development of this proposal.

The proposed project seeks to evaluate the effects of providing tailored support for food companies to implement best practice policies for improving population nutrition. The intervention design will be based on a framework for advocacy developed by the World Health Organization (WHO) (26), other relevant literature and resources, and the research team's extensive experience evaluating industry initiatives and interventions. Targeted companies will be the largest food and beverage manufacturers and fast food chains in Australia and NZ. Accordingly, the project has exceptional potential to impact the food environments of almost all Australians and New Zealanders.

5. Study Objectives

The primary objective of this trial is to determine the effects on the nutrient profile (Health Star Rating) of food company product portfolios, of provision of tailored support to companies on their nutrition-related policies and practices (food composition, nutrition labelling, marketing to children, food accessibility), compared to food companies that are not offered the programme (the control). We hypothesise that the tailored support programme will be more effective than no intervention at 24 months' post-baseline.

6. Study Design

The study is a parallel, two-arm, cluster randomised controlled trial (RCT) with food companies as the unit of randomisation. Food companies will be randomised to receive either the intervention (a package of actions designed to support food companies to improve their nutrition-related policies and practices—described below) or no intervention (control).

6.1 Inclusion criteria

The following food and beverage companies will be eligible for inclusion in the trial:

- A company involved in the production of food and/or non-alcoholic beverages
- >$10 million in annual retail sales revenue
- Holding Company or Head Office and manufacturing located in Australia or New Zealand.
    - In cases where a company has head offices in both Australia and New Zealand but manufacturing and/or nutrition-related policy decisions are made primarily in one country, the company will only be included in the primary decision-making country sample.
- Product portfolio of at least 10 products considered by the research team to be amenable to reformulation (defined as a product where composition may be altered to improve nutritional profile and therefore Health Star Rating)

6.2 Exclusion criteria

- Companies that manufacture chewing gum products, sports supplements, or infant formula ***only***
- Companies currently engaged with the research team on similar interventions
- They are supermarkets or retailers/distributors/importers/wholesalers only
- Companies whose product nutrition information is not available in the Nutritrack or FoodSwitch databases and therefore nutritional profile and HSR is unable to be assessed.

6.3 Recruitment

Potentially eligible companies in Australia and New Zealand will be identified using the Euromonitor Passport Database (31). Packaged food and non-alcoholic beverage (soft drink) companies and Chained Consumer Food Service (fast food) will be considered separately. Companies in each of the two industry sectors will be ranked based on their 2019 category market share and sales revenue. Rankings will be conducted separately for Australia and New Zealand and potentially eligible companies will be initially identified.

We aim to recruit a total of 150 companies, which will be randomized to study intervention (n=100) or control (n=50) groups prior to commencement of the intervention. Control companies will not be contacted by the study team during the intervention phase. For companies allocated to the intervention group, contact details for representatives of the company will be obtained from a variety of sources including: i) existing networks of the research team and partner organisations; ii) relevant industry associations and forums; and iii) company websites and social media sites. Targeted company representatives will typically be in the role of nutritionist, regulatory affairs, or external affairs.

We estimate that only half of companies randomised to receive the intervention will participate in the intervention programme. As such, we will identify up to twice the required number of

eligible intervention companies and will approach all companies randomised to the intervention group, to invite them to participate.

Neither intervention nor control companies will be aware of the RCT design. When intervention companies are approached, we will not mention that this study is a RCT. Instead, these companies will simply be invited to participate in the intervention programme. The programme will consist of multiple elements delivered over the period of 12 months (see below). The framework for the study intervention will be the opportunity to engage in a tailored support programme to help improve company nutrition-related policies and practices.

6.4 Study intervention

- **Intervention group**

The intervention period will span 12 months and include a range of actions to engage with intervention companies and support them to improve their nutrition-related policies and practices. Targeted policy areas include product composition (policies and targets for reducing nutrients of concern with respect to reformulation of existing products and development of new products), nutrition labelling (adoption of HSR, voluntary labelling of added sugar and trans fats, and use of nutrient-content claims), marketing to children (policies and practices for reducing the exposure of children to unhealthy products and brands) and product accessibility (policies related to the availability and pricing of healthy versus unhealthy products).

Actions included as part of the intervention will be based on established behaviour change techniques (31) and the WHO framework for practical and successful advocacy, which includes seven key steps: (i) define the situation, (ii) establish goal and objectives, (iii) identify target audiences, (iv) develop key messages to influence target audiences, (v) develop and implement advocacy plan, (vi) engage media interest and (vii) monitor and evaluate (26). The strategies used to engage companies will build on our teams' engagement with companies as part of the BIA-Obesity initiative (22), and existing relevant relationships of our Australian partner organisations.

A core component of the intervention will be a tailored support programme. This will include company-specific reports on the nutrient profile of a company's product portfolio, their adoption of HSR, and their rankings compared to those of competitor companies (using data sourced from the Nutritrack and FoodSwitch databases). Intervention companies will also be provided with detailed and specific advice on ways to improve their other nutrition-related policies and practices that will draw upon a detailed assessment of company policies and areas for improvement, and the provision of exemplars of both international and national good practice in each domain (e.g., case studies of successful product reformulation efforts). Intervention companies will receive relevant customer insight data and where appropriate, will be provided with information on existing networks, workshops, and support mechanisms of relevance to their industry sector in each country. All intervention materials will be developed in partnership with stakeholders with expertise in consumer campaigns and advocacy. The intervention will span 12 months, but study outcomes will be measured at 24 months to maximize the time available for companies to enact changes.

One of the opportunities presented to intervention companies as a reason to engage with the research team, will be input into the development of a nutrition-related awards/recognition programme. The details of the awards/recognition programme will be developed iteratively as part of the study. It is expected to consist of a list of pre-defined pledges that companies will be

encouraged to sign up to, with annual auditing and renewal of pledges and practices. It is envisaged that the awards/recognition programme will be sector-specific, based on best practice evidence from a public health perspective, and will have independent governance arrangements.

- **Control group**

The control group will not be contacted or offered the intervention during the trial. Generic intervention resources produced for the study, including guides, case studies and referral networks, will be made available to control companies at 24-months post baseline. In addition, an overview of intervention outcomes including 'lessons learned' will be offered to all intervention and control companies.

6.5 Randomisation

Eligible companies will be randomised in a 2:1 ratio to the intervention or control arm using a computer-generated randomisation list produced by the study statistician (YJ). Randomisation lists will be concealed until the point of randomisation.

Randomisation will be stratified by country (Australia, New Zealand), industry sector (chained consumer food services, other packaged food and non-alcoholic beverage companies), and company size (greater than or equal to median category revenue, less than median category revenue).

6.6 Blinding

Neither intervention nor control companies will be aware of the RCT design. Due to the nature of the intervention, food companies allocated to the intervention group will be aware of the programme, as will research staff who engage with the companies. Food companies allocated to the control group will not be contacted during the trial intervention period. Outcome assessments on the foods and beverages produced and sold by all trial food companies will be conducted independently using the Australasian Health Star Rating (HSR) nutrient profiling system, and information extracted from country-specific food product databases (New Zealand Nutritrack databases and Australian FoodSwitch database).

6.7 Concomitant interventions

Both intervention and control companies will be free to engage with and become involved with any other interventions they wish. If the research team becomes aware that a participating company is involved with another relevant nutrition intervention or programme, the name of the programme, the date(s), type, and level of involvement will be recorded in the study database.

6.8 Withdrawal criteria

Companies will be free to withdraw from receiving the intervention or engaging with the research team at any point. If, through the course of the study, there are compelling reasons (e.g., emerging and substantial conflicts of interest) for the research team to withdraw companies from participating in the trial, this will be discussed by the Steering Group Committee, and, if agreed, recorded in a study database and noted in all publications.

6.9 Baseline assessments

Baseline assessments will be conducted for all randomised companies utilising publicly available, routinely collected data where possible, including:

- Relevant company demographics and information (company name, key brands, product categories, category market share, category sales revenue, head office location)

- Baseline product portfolio information (number of products, average nutrient content per 100g (energy, saturated fat, sodium, total sugar, fibre etc.), mean estimated HSR, % products displaying HSR)

- Company nutrition-related policies and commitments

6.10 Primary outcome measure

The primary outcome measure will be the nutrient profile (measured using the Australasian Health Star Rating (HSR) system) of the foods and beverages produced and sold by participating food companies at 24 months post-baseline.

In 2014, New Zealand and Australia adopted the HSR, a voluntary, interpretive front-of-pack nutrition labelling system. HSR rates the nutrition content of packaged food and beverages in half-star increments from half a star (least healthy) to five stars (most healthy). The number of stars displayed is calculated based on the energy, saturated fat, total sugar, sodium, and fruit, vegetable, nut, and legume (FVNL) levels in a product and, in some instances, the protein and fibre content (32). The most recent version of the HSR calculator will be used. The nutrient data to estimate HSR will be extracted from the New Zealand Nutritrack and Australian FoodSwitch databases, which contain annually updated Nutrition Information Panel values, ingredients, and labelling information for packaged products available for sale in major supermarket stores each country.

6.11 Secondary outcome measures

The following secondary outcome measures will also be collected and assessed:

- Nutrient profile (measured using the HSR system) of the foods and beverages produced and sold by participating food companies at 12-months post-baseline.
- Nutrient content (including sodium, sugar, and saturated fat) of the foods and beverages produced by the food companies at 12- and 24 months post-baseline. The nutrient data will be extracted from the New Zealand Nutritrack and Australian FoodSwitch databases.
- Display of HSR labels on packaged foods and beverages produced by the food companies at 24 months post-baseline.
- Company nutrition-related policies and commitments at 24-months post-baseline, measured using the validated BIA (Business Impact Assessment)-Obesity tool (22). Publicly available data related to company policies and commitments to improve population nutrition will be assessed at baseline. Surveys (control and intervention companies) will be used to collect data at 24 months post-baseline. Policy areas include product formulation, product labelling, marketing to children and accessibility (price and availability) of healthy and unhealthy food.
- Company engagement with the intervention and reported, mechanisms, enablers, and barriers to improving nutrition-related policies and practices will be measured via the process evaluation interviews and surveys. Data collection for intervention food companies will occur via survey at baseline and 24 months post-baseline. Control companies will receive a survey at 24 months post-baseline only. Representatives from selected intervention and control companies will be invited to participate in in-depth interviews at

24 months post-baseline. Key indicators will be change relative to baseline in company prioritization and motivation for change, and change mechanisms and resources.

- Information on resources used to develop the awards/recognition programme, implement the intervention, and those accrued by intervention companies will be collected using resource use questionnaires. Resource use data and the primary outcome estimate will be used to conduct a within-trial cost-effectiveness analysis and a modelled analysis incorporating the population health impact of the intervention.

6.12 Schedule of intervention and follow-up

Companies will be approached in the first half of 2021 and the intervention will start from Q2 or Q3 2021, and will run for 12 months.

Trial assessments will be undertaken at baseline, and at 12 months and 24 months post-baseline [Table 1].

In New Zealand, the 2019 Nutritrack dataset will be used for baseline assessment of the primary outcome, and the 2022 and 2023 datasets (collected Q1/2 each year) will be used for the 12-month and 24-month primary outcome assessments. In Australia, the 2019 FoodSwitch dataset will also be used for baseline assessment of the primary outcome, and the 2021 and 2022 datasets (collected Q4 each year) will be used for the 12-month and 24-month primary outcome assessments. Data collection was disrupted in both countries in 2020 due to COVID-19, and thus the 2019 datasets were selected for use as a baseline.

Table 1: Details of follow-up

Timing		**0 weeks (2021)**	**12 months (2022)**	**24 months (2023)**
Description	Screening + Engagement (intervention companies only)	Baseline data collection + Randomisation (all companies)	Interim follow-up (all companies)	Final follow-up (all companies)
Approach to intervention company				
Obtain intervention company representative contact details	✓			
Send introductory email and follow-up to seek engagement	✓			
Confirm engagement with programme	✓			
Company description				
Company demographics		✓		
Product portfolio information		✓		
Outcome assessments				
Nutrient profile of company product portfolio (mean Health Star Rating)		✓ *(2019 datasets)*	✓ *(2022 dataset NZ, 2021 dataset Aus)*	✓ *(2023 dataset NZ, 2022 dataset Aus)*
Nutrient content (including sodium, sugar, and saturated fat) of the foods and beverages		✓	✓	✓
% products displaying HSR		✓		✓
Nutrition-related policy and commitment scores (BIA-Obesity assessment)		✓		✓
Level of company prioritization and motivation for change; enablers and barriers		✓ *(intervention companies only)*		✓
Resources associated with intervention and relevant actions undertaken by control companies			✓ *(resource use data for intervention company actions collected over the 12 months of the intervention*)	✓

7. Statistical Considerations

7.1 Sample size

A total of 150 food companies across both countries (intervention n=100, control n=50) will provide 90% power at a 5% level of significance to detect a minimum 0.48-unit difference between two randomised groups in the mean HSR of all packaged food and beverage products at the end of intervention, assuming a mean HSR of products of 2.95, a standard deviation (SD) of 1.25, and an intra-cluster correlation (ICC) between products produced by the same company of 0.4. This effect size would constitute an approximate 16% increase in the star rating (healthiness) of foods produced by the intervention companies compared to the foods produced by the control group companies.

We estimate that about half of the intervention companies will participate in the intervention programme, which will reduce the effective sample size. A total of 100 companies (50 intervention and 50 control companies) will provide 80% power to detect the expected effect size on the primary outcome under the same assumptions.

7.2 Statistical analyses

Trial data collected from both countries will be stored in secure study databases before being merged and analysed by the study statistician at NIHI. Statistical analysis will be performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

Data analyses will be carried out on an intention-to-treat (ITT) basis. All 150 randomised companies will be included in the primary ITT analysis. A per-protocol (PP) analysis will also be conducted including only those intervention companies who participate in the intervention programme, defined in this instance as agreement to participate in the programme and attendance at minimum one meeting regarding the intervention. A statistical analysis plan prepared by the study statistician (and agreed upon by the Steering Committee) will be prepared a priori. The CONSORT 2010 statement (33) with extension to cluster randomised trials guidelines will be followed when reporting the main trial results.

7.2.1 Baseline characteristics

Baseline data collated for all randomised companies will include:

- Company demographics and information (company name, key brands, product categories, category market share, category sales revenue, head office location)
- Baseline product portfolio information (number of products, average nutrient content per 100g (energy, saturated fat, sodium, total sugar, fibre etc.), mean estimated HSR, % products displaying HSR or other nutrition label)

Data collected at both company and food category level will be summarised descriptively by treatment group. Continuous variables will be presented as numbers of observations, means, standard deviations (SD), medians and ranges. Categorical variables will be presented as frequencies and percentages. Simple tests comparing two groups at baseline will not be undertaken as per the CONSORT guidelines. Such tests also do not consider the clustered nature of the data in a cluster randomised trial.

7.2.2 Intervention effects

All food companies will be included in the group they were allocated to, in order to determine the effects of the provision of tailored support to food companies on their nutrition-related policies and practices, compared to no intervention. Both primary and secondary efficacy outcomes will be tested between intervention and control groups using generalised linear mixed models. The fixed effects will include treatment group, stratification factors, baseline outcome values, and key food categories. Food company will be included as a random cluster effect. The size of any intervention effect will be estimated overall and by key food categories. Model-adjusted group differences will be reported with 95% confidence intervals and p-values, and the ICC coefficients will be estimated. Statistical tests will be two-sided at a 5% significance level.

Pre-specified subgroup analysis will be conducted for each country separately. A secondary analysis will examine only products available over the full duration of the intervention period.

7.2.3 Economic analyses

Resource use associated with the co-production components of the intervention and collected from intervention companies will be assumed to represent the incremental costs for the intervention. At 24 months post intervention, the control companies will also be asked (during the process evaluation in-depth interviews and questionnaire) about relevant actions taken to improve nutrition related policies and practices over the last 24 months and associated resource use. Resource use data analysis will be completed on an ITT basis and complemented with a per protocol (PP) analysis. These will be reported as the numbers of observations, means, standard deviations (SD), medians and ranges. Both the within-trial and modelled cost-effectiveness analyses will use the treatment effects reported using the ITT and PP analyses. Any uncertainty associated with resource use and treatment effects will be accounted for using Monte-Carlo simulations (using the Microsoft Excel add-in Ersatz (34)) and all results will be presented with 95% uncertainty intervals. A detailed economic evaluation protocol will be developed and agreed upon by the Steering Committee.

7.2.4 Procedures to account for missing data

We do not anticipate missing data for the primary outcome, which will be measured independently using the Australasian Health Star Rating (HSR) nutrient profiling system applied to the foods and beverages produced and sold by the food companies included in the study. The nutrient data to estimate HSR will be extracted from the New Zealand Nutritrack and Australian FoodSwitch databases directly, both of which contain annually updated Nutrition Information Panel values, ingredients, and labelling information for packaged products available for sale in major supermarket stores in each country.

Generalised linear mixed models will also take into account any missing data at the product level using maximum likelihood methods, assuming they are missing at random.

Missing resource use data will be handled using various methods and guided by the most likely mechanism for missing data (e.g., data missing at random, covariate dependent missing etc.) (35).

7.2.5 Interim analyses

No interim analysis will be undertaken during the trial. All analyses will be conducted following completion of the 24-month intervention period.

7.3 Data management

7.3.1 Nutritrack

The Nutritrack database is maintained by The National Institute for Health Innovation (NIHI) and owned by Auckland UniServices Limited at The University of Auckland. Annual, systematic surveys are undertaken by trained fieldworkers in four supermarket stores in the Auckland region at the same time each year, enabling tracking of labelling, ingredients and nutrient composition of New Zealand packaged food and beverage products over time.

Trained fieldworkers will use a customised smartphone application (app) to take photographs and collect information directly from all foods and non-alcoholic beverages displaying a Nutrition Information Panel (NIP) in four supermarket stores (New World, 4Square, Countdown, and PAK'nSAVE) in Auckland between February and July in 2021, 2022 and 2023. Data from photographs will be entered into a secure, online database by trained staff. Products will be categorised in a hierarchical structure into 15 food groups, 59 categories, and 177 subcategories using a standardised global system.

Quality checks will be undertaken on a random 15% sample of products where data entered in all product fields will be compared with source photograph for accuracy. Reports will also be run across all products to identify outlier values, ensure complete and correct NIP data, and to maximise consistency of the categorisation of products over time. Data accuracy across critical fields will be monitored during and after data collection each year to maximise accuracy of data collection and entry.

Nutritrack data will be entered, stored and backed-up in a secure manner on a server at NIHI. Access to all study data will be restricted to research staff directly involved in conducting the study. Computerised information will be password protected and hard copy information kept in a locked filing cabinet.

7.3.2 FoodSwitch data

The FoodSwitch dataset contains nutrient information obtained directly from the NIP of all packaged food and beverage products available for sale from five large supermarket retailers in Sydney, Australia (Woolworths, Coles, Aldi, IGA and Harris Farm). Data are collected by trained personnel during the months of August to November each year. For each product, the product name, package size (g), and nutrient content per 100g/mL and per serve are recorded. Food and beverages are classified according to a hierarchal system to classify products into major categories (e.g., dairy), minor categories (e.g., milk), major subcategories (e.g., soy milk) and minor subcategories (flavoured soy milk) (36, 37).

7.3.3 BIA-Obesity

Assessment data relating to food company policies will be collected from publicly available information obtained from company websites and other online sources, or directly from company representatives (at follow-up only). Although individual participant information may be collected to facilitate communication and to arrange any phone calls or meetings as necessary, no additional identifying information will be collected throughout the process. Names of company representatives will not be released. In some cases, companies may request that commercial in confidence information that they provide to the research team be used only for the purposes of the study and scoring using the BIA-Obesity tool, but not for other purposes.

7.3.4 Process evaluation

For ease of consultation with colleagues and completion, surveys will be paper-based (fillable PDF) and emailed to company representatives to fill out via computer or legibly by hand. Each company will be assigned a unique study ID which will appear on the survey. Once completed, company representatives will be asked to (scan if completed by hand) and email the completed survey to the research team. Scanned email responses and survey will be saved on a secured restricted folder at The University of Auckland or Deakin University.

Data from completed surveys will be manually entered by the research team into a data entry programme. Data entry personnel will be identified from the members of the research team, and will be trained if necessary. Completed survey questionnaires will be checked by a member of the research team before data entry starts. Any identifying information other than the particiant ID number will be detached from questionnaires and the data entry program will keep confidential information in a separate file if entered. Responses will remain linked to the allocated participant ID. Data entry will be done by another member of the research team using a data entry program (i.e. REDCap). The data entry program (e.g., REDCap) is only accessible to the responsible research team members and to no one else. This is essential for the confidentiality of data. Another member of the research team will check entered data for the purpose of identifying typing errors, missing values, and overall quality of data entry. Following survey data entry completion, raw data will be extracted from REDCap as a .csv file for analysis and storage, and then deleted from the data entry programme.

In person or virtual (e.g., Zoom) interviews will be audio and video recorded. Audio files will be transcribed verbatim by the research team. Identifiable audio files and transcripts will be preserved for the minimum required period (see below). De-identified data only will be reported in any publicly available research outputs.

7.3.5 Economic evaluation

Resource use data collection tools will be developed in Microsoft Excel to capture the costs related to the implementation of the intervention. This data will be captured monthly by the study project managers and relevant study invoices. Resource use questionnaires will be developed in Excel to collect data tailored to the actions being taken by the intervention companies and will be collected at each of the six intervention sessions. A more detailed resource use questionnaire will be developed in Qualtrics and collected at 12 months and 24 months.

All study data will be stored and backed-up securely at The University of Auckland or Deakin University as appropriate (on a password protected share drive). Paper-based data will be stored in a locked filing cabinet. Only members of the research team will have access to the stored data. All reports from the study will be written in a way such that no individual companies can be identified.

7.3.6 Record retention policy

New Zealand paper records, electronic files, and source documents will be retained for 6 years from the termination date of the study, in accordance with the requirements of the Privacy Legislation and the Health (Retention of Health Information) Regulations 1996.

Australian research data will be retained for a minimum of 5 years from the date of publication, in accordance with the Australian Code for the Responsible Conduct of Research (2018). Records relating to the administration of the research project will be retained for a minimum of 7 years, in accordance with the Deakin University's Research Data and Primary Materials Management procedure

7.3.7 Data sharing policy

Because of commercial and legal restrictions on the use of copyrighted and commercial in confidence material it will not be possible to share data openly which reveal product or company names or carry a risk that individuals could be identified. However, redacted versions of study datasets may be made available subject to a licensed agreement that they will be restricted to non-commercial use. Requests to access Nutritrack should be directed to The National Institute for Health Innovation at the University of Auckland at enquiries@nihi.auckland.ac.nz. Requests to access FoodSwitch, should be directed to Fraser Taylor, Managing Director for Foodswitch ftaylor@georgeinstitute.org.au or foodswitch@georgeinstitute.org.au. Data will be shared between Australia and New Zealand research teams using Syncplicity, a secure file sharing and file synchronisation service. New Zealand de-identified data will be destroyed from Australian-owned storage and servers immediately following publication (anticipated September 2024). A data sharing agreement has been signed by both University of Auckland and Deakin University (October 2022)

7.4 Ethical Approval and Consent

7.4.1 National ethics approval

The University of Auckland Human Participants Ethics Committee (UAHPEC) has approved the New Zealand trial (Ref number: UAHPEC3384, approved 15 February 2021).

The Deakin University Human Research Ethics Committee (DUHREC) has approved the Australian trial (Ref number: HEAG-H 236_2020, approved 5 January 2021)

7.4.2 SCOTT committee approval

No medication will be administered as part of this study; therefore, SCOTT approval is not required.

7.4.3 Informed consent

The primary outcome data for the study are publicly available, collected independently (via annual Nutritrack and FoodSwitch data collections), and do not rely on company consent. As such, informed consent to be included in the REFORM study will not be sought from control companies at baseline. Baseline assessments will be conducted for control companies using publicly available, routinely collected data where possible including: relevant company demographics and information; baseline product portfolio information; company nutrition-related policies and commitments.

However, intervention companies will be approached and invited to contribute to the study by engaging with the research team on various aspects, including development of the proposed awards/recognition programme, the nature of their company nutrition policies, perceived barriers/enablers to change, and resource usage related to the interventions. For these contributions (referred to as "participation"), we will seek informed consent from company representatives. The decision by companies to engage ("participate"), or not, with the research team and study intervention, will be entirely voluntary.

Companies will be asked to nominate a contact person for the research team. This contact person will be introduced to the study, via email or phone conversation. At this point, they will be asked to sign a Plain Language Statement/Individual Consent Form and Organisational Consent/Permission Form, and return it to the research team. It will be made clear that even though a company may choose to participate in the research, the company representative can choose not to. They will also be informed of their right to withdraw from "participating" in the study at any time by communicating that to the research team, but will be informed that the company will still be included in the study based on publicly available data related to the company, and interview data with the company if they withdraw over one month after interviews are conducted. Company representatives will also be provided with the contact information of the principal investigators and the Office of Research Ethics. Although individual participant information may be collected to facilitate communication and to arrange any phone calls or meetings as necessary, no additional identifying information will be collected throughout the process. Names of those involved in the study will not be released.

Control companies will not be contacted by the study team during the intervention phase. At 24 months post baseline, control companies will be invited to provide information on nutrition-related policies and practices, following a similar informed consent process, and following a similar data collection process, as outlined above for intervention companies at 24 months.

8. Assessment of Safety / Adverse Event Reporting

8.1 Adverse events

No adverse or serious adverse events are anticipated and thus such data will not be collected in this trial.

9. Clinical Supplies

No clinical supplies are used in this study.

10. Relevance to Health

Advocacy is the process of influencing people and organisations to create change (26). Coupled with direct support for change, advocacy can potentially lead to improvements in corporate behaviours and industry practices that are currently misaligned with health (27). Our experience strongly suggests that many large corporations in the food industry are keen to shift their practices towards healthier policies and products, particularly in response to consumer opinion and a desire to maintain brand reputation. However, little evidence exists to describe the effects of advocacy and support programmes on food company behaviour (28).

This large cluster randomised controlled trial will establish the effects of a tailored support programme for food companies on their nutrition-related policies and practices (food composition, nutrition labelling, marketing to children, healthy food accessibility) compared to a control condition. If effective, the programme could be maintained by government, non-government, or consumer organisations, and/or adapted for use by other countries/regions as resource to promote improvements in corporate behaviours and food industry practices.

11. Dissemination of Results

11.1 Trial registration

The trial will be registered online on the Australian New Zealand Clinical Trials Registry https://www.anzctr.org.au/

11.2 Study participants

Companies included in the study will be informed about the study results via a plain language summary of the results sent to them just prior to the publication of the study results. A plain language summary will also be published on relevant institutional websites. This will be made available to all food industry stakeholders.

11.3 The public

The public will be informed about the trial via posting of the research findings on the Universities' and other relevant websites, both national and international. Opportunities to make presentations to local, national, and international audiences will be actively pursued. Another dissemination pathway will be media releases (national and international) at the time of journal publication.

11.4 Academic/professional colleagues

Academic/professional colleagues will be informed about the trial via publication in international journals. Less formal feedback will be given to researchers via the investigators' participation in the national and international research community. Opportunities to make presentations to local, national and international audiences will be actively pursued.

11.5 Health service funders and providers

Academic papers and summary reports will be distributed to key stakeholders. In New Zealand this will include, but is not limited to, the Ministry of Health, the Health Promotion Agency, relevant non-government organisations, and public health professionals. In Australia, this will include the Australian Government Healthy Food Partnership (HFP), the Department of Health, Health Promotion Agencies including VicHealth, and non-government organisations such as the Obesity Policy Coalition. Internationally, we will disseminate information to groups such as the WHO.

11.6 Iwi/ Māori

Dissemination of findings to Māori organisations, media and community groups will be guided by our Māori partners involved in the DIET programme. Likely dissemination avenues include Toi Tangata's Hui-a-Tau, the annual Activity and nutrition Aotearoa (ANA) conference and Māori Public Health Association symposium.

11.7 Pacific Island communities

Dissemination of findings to Pacific Island Community organisations, media and community groups will be guided by our Pasifika partners involved in in the DIET programme.

11.8 Aboriginal and Torres Strait Islander peoples

The Australian Code for Responsible Conduct of Research, requires that researchers 'report to Aboriginal and Torres Strait Islander peoples on the outcomes of research in which they have

engaged', recognising, valuing and respecting the diversity, heritage, knowledge, cultural property and connection to land of Aboriginal and Torres Strait Islander peoples.

12. Administrative Section

12.1 Adherence to the protocol

Except for a change that is intended to eliminate an immediate hazard to participants, the approved protocol will be conducted as described. Any significant protocol deviation will be documented.

12.2 Protocol revision procedures

All revisions will be discussed with, and approved by, the Study Steering Committee. If the revision is an "administrative letter", the principal investigator will submit it to the appropriate Ethics Committee for their information. If the revision is an "amendment", the principal investigator will sign it. The principal investigator will submit the amendment to the appropriate Ethics Committee for review and approval or favourable opinion prior to implementation. Documentation of approval signed by the chairperson or designee of the Ethics Committee will be sent to the principal investigator. This should be filed in the study files and copies where appropriate sent to relevant sites.

If an amendment substantially alters the study design:

- the consent form will be revised and submitted to the Ethics Committee for review and approval or favourable opinion.
- participants currently "participating" in the study, if they are affected by the amendment, will be contacted by telephone and the amendment discussed and verbal consent re-obtained.
- the revised consent form will be posted to participants currently "participating" in the study if they are affected by the amendment.

All revisions will be discussed with, and approved by, the Principal Investigators and project team.

12.3 Monitoring/ Source document verification

No medication will be administered as part of this study, therefore monitoring/source document verification is not required.

12.4 Data confidentiality and security

NIHI stores data either on University of Auckland-owned storage and servers, or on cloud services operated by a vendor with whom the University of Auckland have a contractual relationship. Data stored on the University of Auckland storage and servers will be managed in accordance with appropriate NZ Information Security Manual (NZISM) guidelines and relevant legislation including the Privacy Act 2020. Data stored using cloud services is maintained by the vendor and their security is assessed by 1). Relevant vendor certification or accreditations, 2). Independent audits of services conducted by 3rd parties, and 3). University of Auckland performing audits to test the vendor services.

Deakin University data will be stored securely to protect against theft, misuse, damage, or loss, and stored in an indexed and retrievable form, for the required retention period. Storage and management of information which might potentially identify a person must comply with the Public Records Act, 1973 (Vic), Privacy and Data Protection Act 2014 (Vic), Privacy Act 1988

(Commonwealth) and the Health Records Act 2001 (Vic) where relevant. It must also take account of professional standards and contractual arrangements, including agreements entered into with research participants.

Data to be shared between Australian and New Zealand research teams will be stored and shared securely via Syncplicity.

12.5 Reporting schedule

The principal investigator will provide annual reports of the progress, or completion, termination, or discontinuation, of the study to the relevant Ethics Committee, and to the HRC and NHMRC, the principal funders of this trial.

12.6 Record retention policy

Study records and source documents from the New Zealand arm of the trial will be retained for the maximum period required by the New Zealand Privacy Legislation and the Health (Retention of Health Information) Regulations 1996 (10 years from data lock). Staff involved in the trial will not destroy any records associated with the trial, without the prior approval of the principal investigator. If the principal investigator or any co-investigators withdraw from the study (e.g., relocation, retirement), any records they hold will be transferred to a mutually agreed upon designee (e.g., another co-investigator). Notice of such transfer will be given in writing to the Director of NIHI.

Australian research data will be retained for a minimum of 5 years from the date of publication, in accordance with the Australian Code for the Responsible Conduct of Research (2018). Records relating to the administration of the research project will be retained for a minimum of 7 years, in accordance with the Deakin University's Research Data and Primary Materials Management procedure. Research data and materials will be stored securely to protect against theft, misuse, damage or loss, and stored in an indexed and retrievable form. The principal investigator is responsible for disposal of materials from research work. Disposal of research data after appropriate retention periods will be undertaken in compliance with the required safety and environmental standards and in accordance with legislative, confidentiality and other requirements to ensure that data cannot be reused in an unauthorised manner.

12.7 Ownership of data and publication policy

NIHI will have the responsibility for storage, protection, and retrieval of New Zealand study data and merged primary outcome datasets. GLOBE will have the responsibility for storage, protection, and retrieval of Australian study data and resource use data. The Steering Committee will have the responsibility for the safe guardianship and use of the data.

Authorship of study publications will be based on the ICMJE authorship criteria (38). Study participants, the research assistants at Research Centres, members of the Management Committee or Steering Committee who are not named authors, and study sponsors will be acknowledged in the final report and in all publications and presentations resulting from this trial.

13. References

1. Ministry of Health. Health loss in New Zealand 1990–2013: A report from the New Zealand burden of diseases, injuries and risk factors study [Internet].2016.
2. Al-Yaman F. The Australian Burden of Disease Study: impact and causes of illness and death in Aboriginal and Torres Strait Islander people, 2011. Public Health Res Pract. 2017;27(4):e2741732.
3. Australian Bureau of Statistics (ABS). Australian Health Survey: Nutrition First Results-Food and Nutrients, 2011-12 [Internet]. Canberra: ABS; 2014.
4. Australian Institute of Health Welfare. Overweight and Obesity: An Interactive Insight [Internet]. Canberra: Australian Institute of Health and Welfare . Canberra, Australia; 2019.
5. Ministry of Health. Annual update of key results 2014/15: New Zealand health survey. Wellington: Ministry of Health; 2015.
6. Lal A, Moodie M, Ashton T, Siahpush M, Swinburn B. Health care and lost productivity costs of overweight and obesity in New Zealand. Australian New Zealand Journal of Public Health. 2012;36(6):550-6.
7. Swinburn BA, Sacks G, Hall KD, McPherson K, Finegood DT, Moodie ML, et al. The global obesity pandemic: shaped by global drivers and local environments. The Lancet. 2011;378(9793):804-14.
8. Neal B, Sacks G, Shahid M, Taylor F, Huffman M. FoodSwitch: state of the food supply. Sydney: The George Institute for Global Health; 2019.
9. Luiten CM, Steenhuis IH, Eyles H, Mhurchu CN, Waterlander WE. Ultra-processed foods have the worst nutrient profile, yet they are the most available packaged products in a sample of New Zealand supermarkets. Public health nutrition. 2016;19(3):530-8.
10. Mhurchu CN, Brown R, Jiang Y, Eyles H, Dunford E, Neal B. Nutrient profile of 23 596 packaged supermarket foods and non-alcoholic beverages in Australia and New Zealand. Public health nutrition. 2016;19(3):401-8.
11. Lindberg R, Nichols T, Yam C. The healthy eating agenda in Australia. Is salt a priority for manufacturers? Nutrients. 2017;9(8):881.
12. World Health Organization. Report of the commission on ending childhood obesity. Geneva: World Health Organization; 2016.
13. Swinburn B, Kraak V, Rutter H, Vandevijvere S, Lobstein T, Sacks G, et al. Strengthening of accountability systems to create healthy food environments and reduce global obesity. The Lancet Global Health. 2015;385(9986):2534-45.
14. Australian Government DoH. Healthy Food Partnership 202 [cited 2020 August]. Available from: https://www1.health.gov.au/internet/main/publishing.nsf/Content/working-groups
15. Sacks G, Robinson E. Inside our Food and Beverage Manufacturers: Assessment of Company Policies and Commitments Related to Obesity Prevention and Nutrition. Melbourne: Deakin University; 2018.
16. Jones A, Magnusson R, Swinburn B, Webster J, Wood A, Sacks G, et al. Designing a healthy food partnership: lessons from the Australian food and health dialogue. BMC Public Health. 2016;16(1):651.
17. Knai C, Petticrew M, Durand M, Eastmure E, James L, Mehrotra A, et al. Has a public–private partnership resulted in action on healthier diets in England? An analysis of the Public Health Responsibility Deal food pledges. Food Policy. 2015;54:1-10.
18. Heart Foundation. Heart Foundation Tick n.d. [cited 2020 August]. Available from: https://www.heartfoundation.org.au/programs/heart-foundation-tick
19. He F, Brinsden H, MacGregor G. Salt reduction in the United Kingdom: a successful experiment in public health. Journal of human hypertension. 2014;28(6):345-52.
20. Nutrition Australia Vic Division, Victorian Government. The Healthy Eating Advisory Service The Healthy Eating Advisory Service can help your organisation provide and promote healthier foods and drinks; n.d. [cited 2020 29 August]. Available from: https://heas.health.vic.gov.au/
21. Heart Foundation. Food industry and hospitality n.d. [cited 2020 August]. Available from: https://www.heartfoundation.org.nz/professionals/food-industry-and-hospitality

22. Sacks G, Vanderlee L, Robinson E, Vandevijvere S, Cameron AJ, Ni Mhurchu C, et al. BIA-Obesity (Business Impact Assessment—Obesity and population-level nutrition): A tool and process to assess food company policies and commitments related to obesity prevention and population nutrition at the national level. Obesity Reviews. 2019;20:78-89.
23. Swinburn B, Sacks G, Vandevijvere S, Kumanyika S, Lobstein T, Neal B, et al. INFORMAS (International Network for Food and Obesity/non-communicable diseases Research, Monitoring and Action Support): overview and key principles. Obesity reviews. 2013;14:1-12.
24. Robinson E, Blake MR, Sacks G. Benchmarking Food and Beverage Companies on Obesity Prevention and Nutrition Policies: Evaluation of the BIA-Obesity Australia Initiative, 2017-2019. International Journal of Health Policy Management. 2020.
25. Sacks G, Cameron A, Ananthapavan J, Backholer K, Strugnell C. Global Obesity Centre (GLOBE) External Relationships Guidelines. 2019.
26. World Health Organization. Stop the global epidemic of chronic disease: a practical guide to successful advocacy. 2006.
27. Freudenberg N, Picard Bradley S, Serrano M, Behavior. Public health campaigns to change industry practices that damage health: an analysis of 12 case studies. Health Education and Behavior. 2009;36(2):230-49.
28. Lobstein T, Brinsden H, Landon J, Kraak V, Musicus A, Macmullan J. INFORMAS and advocacy for public health nutrition and obesity prevention. Obesity Reviews. 2013;14:150-6.
29. Trevena H, Petersen K, Thow AM, Dunford EK, Wu JH, Neal B. Effects of an Advocacy Trial on Food Industry Salt Reduction Efforts—An Interim Process Evaluation. Nutrients. 2017;9(10):1128.
30. Trevena H, Thow AM, Dunford E, Wu JH, Neal B. Protocol for a cluster-randomised trial to determine the effects of advocacy actions on the salt content of processed foods. BMC public health. 2015;16(1):75.
31. Euromonitor. Passport database: Retail Value RSP and Actual Retail Sales Revenue (AUD and NZD) by Company Shares and Brand Shares for Packaged Food, Soft Drink and Chained Consumer Food Service. 2019.
32. Food Standards Australia New Zealand. Health Star Rating system. Calculator and Style Guide. Version 1 [Internet]. Canberra: Food Standards Australia New Zealand; 2020.
33. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345:e5661.
34. EpiGear International. Ersatz 2016 [cited 2020 9 September]. Available from: https://www.epigear.com/index_files/ersatz.html
35. Faria R, Gomes M, Epstein D, White IR. A guide to handling missing data in cost-effectiveness analysis conducted within randomised controlled trials. PharmacoEconomics. 2014;32(12):1157-70.
36. Dunford E, Webster J, Metzler AB, Czernichow S, Ni Mhurchu C, Wolmarans P, et al. International collaborative project to compare and monitor the nutritional composition of processed foods. Eur J Prev Cardiol. 2012;19(6):1326-32.
37. Coyle D, Rdanuko R, Singh S, Huang P, Wu J. Variations in Sugar Content of Flavored Milks and Yogurts: A Cross-Sectional Study across 3 Countries. Current Developments in Nutrition. 2019;3(6).
38. International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors n.d. [cited 2020 9 September]. Available from: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
39. World Medical Association. World Medical Association Declaration of Helsinki - Ethical principles for medical research involving human subjects: World Medical Association; 2018 [cited 2020 9 September]. Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

14. Study Acknowledgement

STUDY ACKNOWLEDGMENT

I have read the protocol and agree that it contains all necessary details for carrying out the study as described. I will conduct this protocol as outlined therein and will make a reasonable effort to complete the study within the time designated.

I will provide copies of the protocol and access to all information to study personnel under my supervision. I will discuss this material with them to ensure that they are fully informed about the treatment and the study.

I understand that the study may be terminated or enrolment suspended at any time if it becomes necessary to protect the best interests of the study participants.

5 July 2021

Investigator's printed name and signature — Date

Address of study site:
National Institute for Health Innovation, University of Auckland, Private Bag 92019, Auckland Mail Centre, Auckland 1142, New Zealand

5 July 2021

Investigator's printed name and signature — Date

Address of study site:
221 Burwood Highway, Burwood VIC 3125, Australia

15. Appendix 1 – Terms of Reference

15.1 Steering committee

The Steering Committee will consist of all named investigators on the New Zealand and Australian grant applications, and will provide strategic guidance for the trial including development of and adherence to the study design, approval of the study protocol, statistical analysis plan, presentation and publication of main results. The Committee will meet as required during study development, then at least once every three months (or more frequently if required) from start-up to review problems and issues raised by the Study Management Committee. Members may attend the meetings or participate via conference call.

15.2 Study management committee

The Study Management Committee will be responsible for the daily operation of the study, and will develop study materials, deal with study problems, recruitment, and logistical issues. Meetings will be held monthly while the study is in development, then as required when the study is underway. Members may attend the meetings or participate via conference call.

16. Appendix 2 – Informed Consent Procedures and Forms

16.1 Informed consent

The primary outcome data for the study are publicly available, collected independently (via annual Nutritrack and FoodSwitch data collections), and do not rely on company consent. As such, informed consent to be included in the REFORM study will not be sought from control companies.

However, companies will be approached and invited to contribute to the study by engaging with the research team on various aspects, including development of the proposed tiered Awards/recognition programme (intervention companies only), the content of their nutrition policies, perceived barriers/enablers to participation, and resource usage related to the study. For these contributions (referred to as "participation"), we will seek informed consent from company representatives. The decision by companies to engage ("participate"), or not, with the research team and study intervention will be entirely voluntary.

Companies will be asked to nominate a contact person for the research team. This contact person will be introduced to the study, via email or phone conversation. At this point, they will be asked to sign a Plain Language Statement and Organisational Consent Form and return it to the research team. The contact person will also be informed of their right to withdraw from "participating" in the study. They will be assured that they can stop participating in the research process at any time by communicating that to the research team, but will be informed that the company will still be included in the study based on publicly available data related to the company and interview data up to one month after interviews are conducted (if applicable). Company representatives will also be provided with the contact information of the principal investigators and the Office of Research Ethics. Although individual participant information may be collected in order to facilitate communication and to arrange any phone calls or meetings as necessary, no additional identifying information will be collected throughout the process. Names of those involved in the study will not be released.

The Plain Language Statement will outline:

- The purpose of the study.
- An explanation of who the researchers are.
- The length of time of the study
- How we plan to interact with them for the purpose of gaining input into the proposed Awards/recognition programme, providing tailored support and assessment processes
- The potential risks/benefits

The potential participant will be informed (refer information sheet) that:

- The supply of information provided by them is entirely voluntary.
- They have the right to withdraw from "participation" in the study at any time by communicating that to the research team. They will also be informed that the company will still be included in the study based on publicly available data related to the company and interview data up to one month after interviews are conducted (if applicable).

The participant will be made aware (refer information sheet) that:

- Although individual participant information may be collected to facilitate communication with the company, no additional identifying information will be collected throughout the process.
- Names of those involved in the study will not be released
- Paper copies of information collected will be kept securely and all computerised information will be password protected on a computer.
- No one, other than the study investigators and people that may audit the data (e.g., the study monitor) will have access to participant data.
- All information will be published or presented in a way that no individual can be identified.

Appendix 3 – Study Intervention Components

Overview of intervention components

Accreditation Program

Food companies will be given the opportunity to have Input into criteria and processes for a proposed Accreditation Program

Consumer insight data
Facilitate customer insight research specific to the accreditation programme, which could be shared with food companies

Provision of resources

Product portfolio analysis:
- Mean HSR (based on updated HSR algorithm)
- Nutrient content (sugar, sodium, saturated fat etc)

Nutrition-related policy and commitments analysis
- BIA-Obesity assessment criteria

Best practice exemplars
- Local
- International

Internal support / influence
- Presentations
- Workshops

Modelling potential health savings from nutrition practice changes (to be explored)

Consumer Insight Data
- International food policy survey
- Population-level research from existing sources

Broker

To relevant service providers, Eg:
- The George Institute (FoodSwitch)
- CSIRO (FoodTrack and Nutritics)
- Nutrition Australia
- Food tech (eg. Quality Associates, Food Innovation Australia)
- Market research companies (consumer insight data)

17. Appendix 4 – Proposed REFORM Intervention Timeline

Activity	2021				2022				2023				2024			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Recruitment and engagement																
Intervention delivery (staggered start)																
Follow up for Intervention and Control:																
HSR, nutrient profile and labelling indicators		Baseline				12-mth follow-up				24-mth follow-up						
Policy and commitment indicators (BIA-Obesity Assessments)		Baseline								24-mth follow-up						
Process evaluation		Baseline								24-mth follow-up						
Economic evaluation						12-mth follow-up (intervention group only)				24-mth follow-up						
Data analysis																
Knowledge Translation																

18. Appendix 5 - Declaration of Helsinki

WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (39)

Preamble
1.The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with *consideration* of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles
3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits
16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals
19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols
21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees
23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality
24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent
25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo
33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions
34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results
35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice
37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

19. Appendix 6 – Summary of Protocol Amendments

Page	Section heading	Amendment
6	Study Management Committee Members	Jacqui Grey added as PM for NZ and Jasmine Chan added for NZ
41	Study acknowledgement	This was signed
6-7	Study Management Committee Members	Josephine Marshall was added, Caitlin Haliburton was added and date added to Stephanie Shen's role when she finished
29	Process evaluation	Video recorded added as the interviews are over zoom (ethics amendment received for this). Changed transcriptions will be completed by a professional company to by the research team.
30	Data sharing policy	Added the following: New Zealand de-identified data will be destroyed from Australian-owned storage and servers immediately following publication (anticipated September 2024). A data sharing agreement has been signed by both University of Auckland and Deakin University (October 2022)
38	Data confidentiality and security	Updated to Privacy Act 2022
44	Informed consent	Added participants have the right to remove data up to one month after the interview commenced.
23	Primary outcome measure	Updated to 'most recent version' of the HSR calculator
