Author's response to reviews

Title: Protocol for a cluster-randomized trial to determine the effects of advocacy actions on the salt levels of processed foods

Authors:

Helen J Trevena (htrevena@georgeinstitute.org.au)
Anne Marie Thow (annemariethow@sydney.edu.au)
Elizabeth K Dunford (edunford@georgeinstitute.org.au)
Jason HY Wu (jwu1@georgeinstitute.org.au)
Bruce C Neal (bneal@georgeinstitute.org.au)

Version: 4 Date: 24 November 2015

Author's response to reviews: see over
Reviewer 1

The follow-up period of 24-months is relatively short on the basis that this time frame may not give enough time for the advocacy process to result in manufacturing practices and therefore enough time to observe a change in sodium content at 12 and 24 months. Statistical significance would require a 12% change which might be difficult for some companies to attain.

Will long term monitoring be added to this design?

Authors’ comments

Thank you. You raise a very valid point. We will assess these time points for both the food composition outcomes and process measures. The process measures should give us an idea of whether anything is happening even if we don’t detect composition changes. We are also working on identifying resourcing to examine the longer term effects.

Reviewer 2

Major compulsory revisions

1. The tense is problematic. Written as something that is going to occur, but the time period has already passed. Recommend writing it up as the methods/protocol but in the appropriate tense. Seen throughout and in particular on page 15, project status section.

Authors’ comments

We agree that the time period has now largely passed. At the time of submission, early April 2015, this was not necessarily the case.

Given that the manuscript is a study protocol all sections, except the section on page 15 ‘Project Status’ were written as something that was going to occur. We believe this tense is appropriate for a study protocol. We have however changed the tense on lines 198-201.

The switch in tense on page 15 to something that had occurred was to provide the reader with an update on what the project had achieved. For example, we had been granted ethics, we had randomised the companies and we had invited participants to join the study.

Clearly, 8-months have now elapsed since the original submission of our manuscript but we feel the tense remains appropriate for the purpose of a study protocol. We will of course accede to an editorial request if our decision proves to be problematic.
2. Time to shelf for a reformulation is about two years. There may be a decrease in sodium mg/100g during the period of the study, but another analysis at 6-12 months out might be useful.

Authors’ comments

Yes, we agree the average cycle of reformulation is about 2 years. We had acknowledged this as a limitation on page 18 lines 361-362 and have revised the text to read “We acknowledge that the study evaluation will focus on the short- and medium-term effects and corporate change may take longer than our study period allows for. However, as part of an ongoing monitoring program we will be able to assess changes in mean salt content post-2016”.

3. Page 7, line 111, what about existing company R&D plans?

Authors’ comments

Thank you, you raise a very good point. The R&D capability of a company is an aspect we included in the survey questionnaire. We sought to understand the level of internal company support, access to internal and external R&D resources, as well as company processes for product development (for example, was a stage gate approach used in the product development process). Understanding the R&D capability of a company but also motivation to invest that R&D in salt reduction is important particularly in the context of voluntary reformulation.

On page 17, lines 339-341 we acknowledge that a key challenge in working with food companies is the risk of non-participation with commercial sensitivities a key barrier. We have specifically included product development plans in the amended text, which now reads “Lack of trust and commercial sensitivities (for example disclosure of product development plans) can be key barriers in this regard.

4. Add more detail on ‘baseline data’ and also how baseline will be compared to future collections. Will you be taking the mean of all available products (baseline + new market introduction)? Will sales/popularity be a factor (sales weighted mean)?

Authors’ comments

Thank you. On page 10-11 (nutritional data) we describe the collection process for nutritional data. Data are collected from all products on the shelves of the supermarkets at the time of collection. As data collection occurs annually we are able to track the nutritional composition of a single product across the years. Therefore, we can assess subsets of products such as only those products available only in all years or products newly-introduced in a given year for example.
The unavailability of market share data for products is a barrier to assessing data by sales weighted mean.

On page 18, lines 363-366 we have added text into the manuscript which reads “However, as part of an ongoing monitoring program we will be able to assess changes in mean salt content post-2016. Lastly, market share data for individual products are unavailable to us and are unlikely to become available as the cost is prohibitive, as well as these data generally coming with restrictions on their use. Weighting of the analyses by sales will not therefore be possible. The systematic collection of data from all products on shelves does however provide for subset comparisons of baseline products available in multiple years and new market introductions.”

5. Page 20, clarify if additional data was systematic and included only if no interview or in all cases (company website, then xyz, then xyz).

Authors’ comments

Thank you. All publicly available data are collected systematically regardless of interview participation. The search for publicly available information pertaining to the interim outcomes was carried out in the same way for all companies.

The manuscript on Page 10, lines 176-178 has been revised to now read: “In addition, relevant information that can be gathered from public sources will be systematically collected and compiled for all companies. For example…….”

Minor essential revisions

1. Is there an official name for the Australian dietary guidelines, consider using it for clarity, page 2 and page 4 wording is slightly different.

Authors’ comments

The official name is ‘Australian Dietary Guidelines’. The text has been amended on page 2 and page 4 to be consistent (‘Australian Dietary Guidelines’).

2. Table 1, ‘receivership’ and ‘special foods’ may not be common to the reader, add footnote definition

Authors’ comments

Thank you. Footnote definitions have been added to the bottom of Table 1.
1 Where a third party is appointed to take responsibility for the company assets. This may occur in a situation where a company cannot meet its financial responsibilities (for instance, insolvency).

2 Includes baby food, meal replacements, fitness and diet products, breakfast beverages, and sport protein powders.

3. Figure 1. Under excluded suggest providing numbers separately for #20 products, importers, and receivership.

Authors’ comments

We have included numbers separately. Excluded for receivership n=1.

4. Line 89. Define ‘other processing’.

Authors’ comments

Other processing includes companies engaged in manufacturing food products not elsewhere classified according to the Australian and New Zealand Standard Industrial Classification (ANZSIC). The Australian Food and Grocery Council report which was used to determine the number of enterprises uses the ANZSIC classification system. ‘Other processing’ is a code specified in the footnote of the original data source. The following link fully explains ‘other food product manufacturing’.


We have added into the manuscript a definition of ‘other processing’. “ - processing not elsewhere classified such as frozen pre-prepared meals, seasonings”.

5. Page 10/11 add specifically how data is collected (company sends, research takes photo etc).

Authors’ comments

Data are collected using a data collector smartphone app developed by The George Institute and which is used by other countries. The on page 10/11 now reads “Data are obtained directly by taking a set of photographs of each product using a smartphone app designed to collect photos of packaged food items. One of the photographs includes the mandatory Nutrition Information Panel (NIP) and is available for a sample of about 20,000 Australian packaged food products each year”.


Authors’ comments

Quantitative data to assess the primary outcome will be completed once in 2016 and will use data that is collected in Q4 of 2015. The manuscript now reads on page 12, lines 224-225 “The primary examination of these outcomes will be after at least 18 months of intervention has been implemented using data collected in Q4 of 2015”.

In addition, page 10, lines 190-191 explain baseline data for the project were collected between September and December 2013, and that data will be collected twice more; September-December 2014 and again in September-December 2015.


Authors’ comments

‘Excess’ has been inserted into the text which now reads “…requiring the excess addition of salt, sugar, and saturated fat during processing..”

Discretionary revisions

1. Consider rewording ‘positive’ and ‘negative’ in the abstract and discussion.

Authors’ comments

Thank you. We have reworded the abstract discussion to now read “A finding of improved food company behaviour will highlight the potential for greater investment in advocacy whilst the opposite result will reinforce…” . We have also reworded the text on page 16, lines 310-311 to read “A finding of improved company behaviour will provide new impetus for the many advocacy groups working in this space and the opposite result…”

2. Page 4, line 40, consumer demand is not acknowledged, consider adding the role consumer demand plays on food companies decisions.

Authors’ comments

Thank you. The manuscript has been revised to acknowledge the role consumer demand plays on decision making. The text now reads “Decisions about the nutritional quality of processed foods and the numbers of foods marketed are taken primarily by food companies to
create and respond to consumer demand and are potent factors shaping the food supply, and thereby food choice [4-9].

3. **Line 49 – ‘very high likelihood’ awkward wording.**

   **Authors’ comments**
   We have changed the wording to now read “In all likelihood excess dietary salt..”

4. **Lines 331-334 - consider addressing sooner in the paper**

   **Authors’ comments**
   Thank you. We have considered adding this sooner.

   Although introduced at a broad level, in the description of the intervention, line 126-127 states the advocacy actions are those commonly used. Framing is one of many possible actions. Given its importance to advocacy, we single framing out for further discussion. The intent of this approach is to provide the reader with a good overview of the study before discussing particular features, in this case framing.

5. **Lines 346-347 – consider addressing sooner in the paper**

   **Authors’ comments**
   Thank you. Lines 347-350 refer to the challenges of measuring advocacy and attribution of impact in a changing environment. Lines 65-66 do introduce the challenges of assessing advocacy in a fast moving environment.

   We consider these issues a limitation but one for which the design of the study should help control the changing environment. On this basis we feel these issues are more appropriately discussed alongside other limitations and strengths of the study.