Author's response to reviews

Title: Protocol for a pilot randomised controlled trial of an intervention to increase the use of traffic light food labelling in UK shoppers (the FLICC trial)

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Response to reviewers

Note to editors:

We have made some small changes to the manuscript that were not prompted by the reviewers’ comments. These changes reflect developments with the pilot trial since submission of the protocol in July. The changes are as follows:

1. We have added details of ethics approval from the University of Surrey, which has now been granted alongside ethics approval from University of Oxford
2. We have updated the ‘conflict of interest’ section to include consultancies conducted by the research centre at the University of Surrey.
3. We have updated the target recruiting date from January 2015 to Spring 2015.
4. We have ensured that description of the intervention complies with the TIDIER checklist (Hoffmann et al., BMJ, 2014).

Editor’s comments:

Please include all the co-authors’ email addresses in the Title page.

Response: These have now been added.

Please include three to ten keywords representing the main content of the article, after the Abstract section.

Response: The keywords have been moved to after the abstract.

Please include an acknowledgement section at the end of the manuscript before the reference list. Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include the source(s) of funding for all authors. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements.

Response: An acknowledgements section has been added.

Reviewer 1:

This paper describes a protocol for a pilot randomised controlled trial of an intervention designed to increase the use of traffic light labelling during supermarket food purchase decisions for pizzas and ready-meals in UK shoppers. The protocol is clearly well thought-out, well-described and the pilot trial described here will be of great value to public health in an extremely policy relevant area.
Major Compulsory Revisions

1.1 - My main concern is that the design of the trial does not appear to be able to take into account factors other than the label that may influence purchasing behaviour. For example, we know that price promotions (particularly "buy one get one free") have a major influence on purchasing behaviour in these food categories, yet I could not find anywhere in this protocol that would allow the effect of price promotions to be taken into account in the analysis. Similarly, it is not clear how the trial will be able to take into account the effects of seasonality, in-store promotions (of various kinds), and the amount of shelf space allocated to particular products. We know that these are all likely to be bigger influences on what people buy than traffic light labels, and so I would have expected more details of how these aspects will be handled. While I understand that some of these factors are more difficult to factor into the analysis than others, data on price promotions should be readily available from the retailer and I would have expected it to be part of the data collection activities. Seasonality should also be able to be accounted for.

Response: We agree with the reviewer that there are a number of external factors (e.g. seasonality, price promotions) that influence purchasing decisions. However, the randomised experimental nature of this study will account for these potentially confounding factors, as they will be experienced by both the control arm and the intervention arm simultaneously. We have added a short section to the discussion to explicitly address this (Lines 375 to 378).

1.2 - p3, line 8: An additional, and critical, objective of traffic-light labelling is to provide information to consumers about the nutritional quality of products. Firstly, this needs to be acknowledged here. Secondly, I would have thought it valuable to assess changes in awareness / understanding of product nutritional information as part of the trial, perhaps as one of the secondary outcomes. The risk is that trials such as this focus so much on changing behaviour, that we might miss other important benefits, such as improvements to understanding of nutritional information which are important from many aspects, including a consumer rights perspective. Linked to this point, it is not clear why the authors are proposing hypothesis 'c' (that the intervention will not change purchasing behaviour outside of the targeted food categories). This needs to be better justified, or else modified in light of my comments.

Response: A line has been added to the introduction to highlight the objective of traffic light labels to provide nutritional information to consumers (lines 59-61). We will be collecting information on participants’ beliefs, attitudes, intention, outcome expectancies and procedural knowledge of traffic light label use in the psychosocial questionnaires that we will be collecting at baseline and twice during the data collection period. This has been clarified under the ‘effect sizes’ section (lines 320-321).

Regarding hypothesis ‘c’, the intervention has been designed to be food category-specific, focussing only on ready meals and pizzas and therefore we hypothesise that it will only impact on food choices within this category. This is the most likely outcome since many of the other food categories do not have sufficient coverage of front-of-pack nutrition labelling for the consumer to use in the way described by the intervention. However, the pilot nature of this study means that it will be possible to explore whether the effect ‘spills over’ to other food categories utilising the secondary outcome variables. This has been clarified in the revised manuscript (Lines 127-132).
1.3 - p5, 2nd last line: Do the authors mean it will not affect the total amount (in grams) of foods purchased? This needs to be clarified. If they do indeed mean total grams purchased, the authors need to check that all ready meals and pizzas weigh the same amount. If they don't all weigh the same, perhaps it would be better to say that "the total number of ready meals / pizzas purchased will not change".

Response: The manuscript has been revised under the secondary outcomes section to clarify that we mean it will not affect the total number (on average) of ready meals and pizzas typically purchased (line 315).

Minor Essential Revisions

1.4 - p4, line 3: "purposes"

Response: Thank you – this has been corrected.

1.5 - p4, line 9 (and elsewhere in the manuscript): please provide metric measures

Response: This has been altered.

1.6 - p4, 4th last line: Perhaps say "may be less aware" or provide a reference to substantiate this assertion

Response: This line has been deleted in response to a comment from reviewer 2.

Discretionary Revisions

1.7 - Page 15, 10 lines from the bottom: The authors mention very briefly that subgroup analyses by socioeconomic status will be conducted to assess potential impact of the intervention on social inequalities. These few lines are the only mention of socioeconomic status in the whole protocol and it reads almost like an afterthought, whereas, in reality, the analysis by SES group could well be the most beneficial aspect of this study. I wonder if it would be useful to integrate a discussion of SES in other parts of the manuscript (perhaps even as an additional objective and hypothesis) and provide a bit more detail of how this analysis will be performed.

Response: We have added a sentence to the ‘outcome measures’ section (lines 293-296) which describes how recruitment and retention rates will be measured for differential rates by socioeconomic profile. We agree that socioeconomic status is an important measure for a pilot trial such as this. However, at this stage we do not know whether the trial design and the intervention is likely to lead to differential recruitment and retention rates or in fact any differential health impacts. Therefore, we do not feel that further discussion in this protocol is appropriate at this stage.

Reviewer 2:

This manuscript presents a protocol for a pilot randomised controlled trial of an intervention to increase the use of traffic light food labelling in UK shoppers. It is important to further our
understanding of the impact of these kinds of interventions on shopping behaviours, especially for those at a higher risk of developing conditions such as obesity and cardiovascular disease. However, I have identified a number of weaknesses within this proposal, particularly in relation to the proposed methodology, which are detailed below. Based on these weaknesses, I would recommend that this manuscript is not suitable for publication.

GENERAL

2.1 - It is useful for reviewers when line numbers are presented as it makes it easier to comment on specific areas of the manuscript.

Response: We apologise that line numbers were not included in the initial submission. They have been added to the revised manuscript.

ABSTRACT

INTRODUCTION

2.2 - Page 3: You state that the intervention is based on current behaviour change literature but do not refer to this literature at this stage. There is no outline of what this behaviour change literature consists of – e.g., which theories are you referring to? What evidence is there for these theories? Why use the behaviour change literature to inform your approach to intervention design and not another approach? What interventions have been used in the past to reduce unhealthy food buying patterns? Have they been effective? If not, why, and why is this approach better?

Response: The information relating to the intervention content is presented later in the manuscript under the heading ‘Intervention’. We intended the introduction section to be a brief introduction to the concepts that will be covered in the protocol, with the main substance of the design included elsewhere. The section entitled ‘Intervention’, includes references to the appropriate literature (Fishbein et al, 2001: Michie et al, 2005, Jensen et al, 2012).

The development of this intervention is based on a review of previously conducted intervention studies that had encouraged the use of nutritional labelling from which the behaviour change techniques being used and the behavioural mechanisms that were being addressed were identified (manuscript under preparation). A number of different theories and mechanisms have been utilised in a range of different contexts and some did not refer to any theory as their basis however, since behaviour change theories and models in the food domain tend to contain a limited range of overlapping mechanisms (Fishbein et al, 2001: Michie et al, 2005) for this intervention, an approach involving selection of the most relevant mechanisms from the various frameworks to effect the desired food-related behaviour was identified as preferable to approaching the design of an intervention from a single theoretical framework or an atheoretical (no theory) standpoint (Jensen et al, 2012).

The actual content of the intervention is further defined in table 3 which details the behaviour change techniques we will be using, the mechanisms we hope to utilise to facilitate the behaviour change and the way in which this is to be operationalised in the intervention itself. In response to this comment we have revised the table to provide more detail and to be clearer about which pieces of intervention content will be static and which will be interactive and also added some clarification to the main body of text in the intervention section.

In terms of the types of interventions that have been done in the past to reduce unhealthy food buying, these are discussed in the manuscript under the ‘Intervention’ section (lines 251-268) in
relation to whether those interventions focussed on ‘inter’ or ‘intra’ category food choices. In the same section we also discuss why we predict that by reducing the amount of systematic processing required for intra-category food choices, the intervention described here may be ‘better’ than what has been done before. However, its effectiveness has not yet been evaluated hence the need to perform this pilot RCT.

2.3 - Page 4: The general structure of this section is difficult to follow

Response: We have made some changes to improve readability.

2.4 - Page 5: study hypotheses are not worded in traditional fashion

Response: We have re-numbered these from ‘a-d’ to ‘H1 –H4’. However, we are not clear how else to address the reviewers’ concern.

METHODS

2.5 - Page 6: Study design. There is no reference for the ‘parallel’ study design, nor any explanation about what this is. In the title of the paper it states this is a randomised study but this is not stated in the study design.

Response: We have added the word ‘randomised’ to the first sentence of the study design (line 138). Details regarding randomisation are in the manuscript under the ‘Recruitment and allocation strategy’ section (lines 169-182). It states that block randomisation will be used stratified by gender and whether or not participants have dependent children to allocate individuals to the intervention or control arm. Researchers will be blind to the randomisation process. Participants in both arms of the trial will be aware that the study is about healthy food purchasing and traffic light food labelling but only one arm will receive the full intervention. By ‘parallel’, we simply mean that this is neither a crossover nor a factorial design. This is a commonly used term in trial design, and the study design for this trial is explicitly stated in the following sections, so this does not have the potential to mislead the reader.

2.6 - Page 6: Setting. It is unclear what ‘facilitating token-based authentication’ means

Response: Through discussion with the participating supermarket that has occurred since submission of this manuscript we have had to change this element of the recruitment process. Therefore, the ‘token-based authentication’ has now been removed from the manuscript. The updated protocol for recruitment is detailed in lines 169-182.
2.7 - Page 6. Figure 2. There are two sets of ‘exclusion’ criteria in figure 2, but you refer to it for presenting both inclusion and exclusion criteria.

Response: This has been amended so the text refers to ‘exclusion criteria’ only (line 163).

2.8 - Page 6: Recruitment and allocation. It is not clear how you will gain access to the loyalty card holders. Has this already been negotiated? What risks are associated with this recruitment strategy (in terms of getting enough numbers for your analysis) – there is also no sample size calculation. Will the participants be told about the true aim of the study or will they be blind too?

Response: Two sentences have now been added to clarify that the recruitment method (initial email contact from the participating supermarket) has already been successfully used in a previous unpublished study (a manuscript is currently under preparation) (lines 178-182). This is a low risk strategy in terms of recruiting enough individuals for the analysis, as we will only be initially contacting 33,000 loyalty card holders from a total database of over 1m. Therefore, if recruitment rates are lower than expected we can contact more loyalty card holders. A sentence has been added to the protocol to clarify this (lines 222-223). The manuscript currently has the following text: “We are aiming to receive approximately 400 complete sets of psychosocial questionnaire data and 1,200 complete sets of electronic sales data. This will allow us to detect an effect size (measured by Cohen’s d statistic) of 0.28 for the psychosocial questionnaire data and 0.16 for the electronic sales data. In general, effect sizes of 0.2 or less are considered ‘small’. The data collected in the pilot trial will allow us to refine our sample size estimates for the main trial.” We feel this is ample description of the sample size calculation for this trial (which is a pilot, so we have no effect size estimates to guide us). Participants in both arms of the trial will be told of the aim of the study – we have made this explicit in the revised manuscript (lines 186-187).

2.9 - Page 8: There is no description about how block randomisation will be used.

Response: This sentence has now been amended as follows: “Block randomisation will be used stratified by gender and whether or not participants have dependent children to allocate individuals to the intervention or control arm” (lines 184-185).

2.10 - Page 8: T0 is stated as one of the time points for data collection but this has not been mentioned when time-points for data collection were presented earlier. Is T0 a data collection time point or does this actually represent T1?

Response: Although electronic sales data will not be collected during T0, psychosocial questionnaire data will be collected at this point. We have modified the section on ‘design and study duration’ to make this explicit (lines 141-142).

2.11 - Page 9-10: Consent. Although at another stage in the method you state ethical approval has been granted, the methods for consenting and subsequently proposing to continue to collect data from individuals who decline to participate or withdraw seems unethical to me.

Response: We will not be collecting any further data from participants who choose to withdraw from the study. For such people, electronic sales data will be censored at the withdrawal date. However,
participants will also be given the option to unsubscribe from study contact. Here, we will no longer contact the participants with emails regarding the study but we will continue to collect electronic sales data (for which they have given us their consent). This is a reasonably common feature of trials and has been approved by the University of Oxford ethics committee.

2.12 - Page 10: Intervention. Although some reference to behaviour change literature is mentioned here, it is presented in a technical manner without any information to help the reader put the terminology into this particular context. What do you mean by ‘mechanism’, for example?

Response: Behaviour change interventions consist of a number of interacting components and each component (or behaviour change technique) has the potential to impact on more than one mechanism. A mechanism is the means by which the behaviour change technique facilitates change. This is well described in the cited references (Jensen et al. 2012; Fishbein et al, 2001; Michie et al, 2005) and in table 3 we have detailed the behaviour change techniques we will be employing (column 1), the behavioural mechanisms likely to be impacted (column 2) and the way in which this is to be operationalised in the intervention itself (column 3).

In terms of the intervention we propose, for example, one of the behaviour change techniques we will be employing is a component which models the desired behaviour for the participant (see table 3, 4th row). This will be provided in the form of a video showing people using traffic light labels to make better choices. This behaviour change technique (Modelling the behaviour) has the potential to impact on a person’s mechanisms of intention formation because by having watched the video they might feel that the behaviour we are asking them to do is more likely to result in a positive outcome for them (outcome expectancies) than they did before watching it; they might feel that it will be easier to perform than they previously thought (self-efficacy) and that they will be able to do it fairly easily (perceived behavioural control). By mapping the likely mechanisms that will be impacted by the behaviour change technique employed, one can identify the appropriate measures to be included in the psychosocial questionnaire to capture the changes in beliefs, intentions and other variables which may mediate/mitigate the behaviour change such as self-efficacy.

2.13 - Page 10: there are no references provided for the evidence demonstrating that people make inter- and intra-category food choices.

Response: It is widely accepted within the food choice domain that people can either make intra-category or inter-category choices depending on their overall goal and this terminology is frequently used in the literature to describe these different choice strategies although there is no one published reference that relates specifically to this. Within the intervention section we say that previous interventions aimed at improving peoples food purchases generally fall into two main groups; a) interventions that encourage healthier eating at a diet level i.e. eat more fruits and vegetables and less fatty foods etc. (inter-category) b) interventions that encourage use of nutritional labels to improve choice between similar products (intra-category) (lines 251-254). This is based on our review of previously conducted intervention studies that encouraged the use of nutritional labelling the manuscript for which is under preparation. In addition, whilst the intervention we propose is targeted at helping people make healthier intra-category decisions (i.e. to use traffic light labels choose a healthier ready meal than they normally would), if as a result of this intervention they in fact end up making inter-category choices this will be ultimately be evidenced by changes in the secondary outcome variables for this study.
2.14 - Page 11: you say that people are ‘required to make a significant investment’ but it is not clear what this investment would be (or if it would be a number of things).

Response: We have amended this to state “Therefore what people are being asked to do requires significant investment of time, effort and motivation and is a clear departure from their typical choice behaviour” (lines 267-268).

2.15 - Page 11: Again it is not clear what is meant by ‘mechanism’

Response: Please see full response to the comment 2.12 above.

2.16 - Page 11: There is no example provided of what an ‘interactive section’ would consist of, nor any information about what the ‘critical stages of the behaviour change process’ are. This lack of information makes it difficult to imagine what the intervention might look like and what aspects of the behaviour change process the intervention will target.

Response: Table 3 itemises all of the elements that will be included in the intervention, the behaviour change techniques upon which they are based, and the behavioural mechanisms that we are hoping to impact. As a result of this comment, table 3 has been further enhanced so that a clearer description is provided of each of the elements in the intervention, and also which of the elements of the intervention are interactive and which are passive. In terms of the critical stages of behaviour change these are included in the second column of table 3 i.e. ‘Belief formation’, ‘Intention formation’, ‘Planning and Goal Setting’ and ‘Adopting and Maintaining Behaviour’. Description of the intervention within this protocol complies with the TIDIER checklist for intervention description recently published in the BMJ (Hoffmann et al., BMJ, 2014).

2.17 - Page 12: the first paragraph seems to belong in the procedure

Response: We agree with the reviewer and have moved this information to earlier in the manuscript, during the description of allocation to intervention or control arm.

2.18 - Page 12: I do not believe that recruitment, data and completeness belongs under the heading ‘outcome measures’

Response: We disagree with the reviewer. Since this is not a full RCT, but a pilot RCT, the outcome measures relate to the study objectives, which include measuring recruitment rates and data completeness rates. This will provide information about whether or not it is feasible to move to a full RCT and we therefore feel that these do belong under the heading ‘outcome measures’.

2.19 - Page 12: The information provided under the heading ‘effect sizes’ does not refer to how ‘effect size’ will be calculated. There is no description of what statistical tests(s) will be used to analyse the data.
Response: The ‘effect sizes’ section has been modified to be more precise about how the effect size will be measured and what exactly will be measured (lines 302-305). Along with information already provided in the appendix, this provides enough information about how the effect sizes will be calculated. Whilst there is no description of the statistical tests that will be used to analyse the data in the ‘effect sizes’ section, there is a description provided in the ‘statistical analysis’ section (lines 359-371).

2.20 - Page 15: the statistical analysis of the outcome data seems to be in an illogical place, as the process evaluation methods is presented between the outcome data section and the statistical analysis section. This is very confusing to follow.

Response: We disagree with the reviewer. The results of the process evaluation are some of the central outcome measures of the pilot trial (similar to the measurements of recruitment rates, data completeness rates etc.) and hence this fits within the manuscript structure where the subheadings of ‘recruitment, retention and data completeness’, ‘effect sizes’, ‘process evaluation: semi-structured interviews’ and ‘process evaluation: web analytics’ are all gathered under the heading ‘Outcome measures’.

2.21 - Page 15: No rationale is provided for analysis on an ‘intention to treat’ basis

Response: We apologise if this was not clear. We have added clarity to the manuscript to explain that we mean that data from those who unsubscribe from the study will still be included in the results (lines 366-367).

2.22 - Page 16: you state that one of the limitations is that loyalty cards can be used by multiple people so it is impossible to link purchases with specific users, and that all purchasing may not be undertaken in the same supermarket. This seems like a large flaw in the study design (which may be partially overcome by the introduction of some consumer-based interviews/questionnaires to attempt to discover the extent to which they have been the sole user of the card and consistently shop in the same supermarket) which potentially renders a large and undefinable proportion of the data collected as invalid

Response: We agree, which is why we have included this as a study limitation. At present it is impossible to know how big a limitation this is to the study design as there are no publicly-available data on loyalty card use within families or households. This is one of many reasons why we are conducting a pilot trial rather than a full trial – we need to discover the limitations of the proposed method (with process evaluations and questionnaire data) in order to evaluate whether the design is suitable to take forward to a full trial. At present, there has never been a UK-based randomised controlled trial conducted using loyalty card data to measure the outcome data. Because of the large number of loyalty card holders in the population and the automated data collection process that loyalty cards provide, this method could provide an extremely valuable source of data for public health experiments. It is therefore valuable to explore the potential of using such data in pilot studies such as this one.
Although you state that it is important to develop interventions to use these tools, it is not clear how you intend to use the findings from this particular study to improve the next phase of the research (e.g., the content of the interventions tested as part of this pilot study)

Response: The ‘study objectives’ section of the manuscript states the following: “The goal of this pilot RCT is to assess the feasibility of a full RCT to measure the effectiveness of an intervention designed to help people use traffic light food labels to purchase healthier ready meals and pizzas. To achieve this goal, the pilot RCT is designed to meet the following objectives: 1. To obtain reliable estimates regarding recruitment, retention and data completion. 2. To produce estimates of the potential effect size (mean and standard deviation [SD]) of the intervention on purchases of ready meals and pizzas (primary outcome). 3. To produce estimates of the potential effect size (mean and SD) of the intervention on purchases of all foods; purchases of fruit and vegetables; and psychosocial variables associated with label use (secondary outcomes). 4. To conduct a process evaluation consisting of semi-structured interviews and web analytics to explore the acceptability of the trial to both participants and the participating supermarket chain, to explore unintended consequences of the intervention, and explore the take up of different elements of the intervention.” We believe this (and then the subsequent explanations of the methods that we will use in order to achieve these objectives) is an adequate description of how we intend to use the findings of this particular study to improve the next phase of the research. The specific example raised by the reviewer (the content of the interventions) will be assessed by a) effect size measurements (did the intervention as a whole have a measurable effect?); b) web analytics (which bits of the interventions where viewed most, and for how long?); c) semi-structured interviews with the participants. We think this is all clearly stated in the manuscript already.

There is no reference number provided for ethical approval.

Response: Apologies for the oversight. This has now been added (lines 413-415).