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 EDITOR’S COMMENTS

In Table 1 please indicate in the title/footnote what the figures represent - are they maximum values or means etc? What are the units of each measurement?

Response: We have updated this table to make it clearer that the numbers indicated are the number of foods that had the different colour lights. We have also added percentages.

On page 7 please give a reason why effect size is relevant here for the intervention group. Usually we are interested in estimates for the control group only and specify a clinically meaningful minimum difference to detect in sample size calculations. For example, you might say that estimates of patient-centred outcomes for intervention and control groups will be calculated so that we can determine that a difference can be seen and that the intervention is therefore likely to have an effect in a future trial.

Response: On page 7 we state the following as an objective of the pilot trial: “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).” We will be measuring the primary and secondary outcomes for both the intervention and control group and comparing differences between them (this is described in the statistical analysis section). To make this objective clearer, we have changed the wording slightly as follows: “To produce estimates of the potential effect size (mean and standard deviation [SD]) of the web-based intervention on purchases of ready meals and pizzas (primary outcome).”

With regard to clinically meaningful minimum differences, there is currently no evidence to quantify the change in purchases of ready meals based on traffic light labels to clinical outcomes, or consumption of different targeted nutrients, or even purchases of targeted nutrients. That is why one of our secondary outcomes is measurement of total nutrients purchased from all foods. By combining results on the effect size of the primary outcome measure and the change in nutrient purchases we should have enough data to estimate clinically meaningful minimum differences for the full trial, but at the moment we are restricted to a sample size estimate based on a small effect size estimated using Cohen’s d statistic. To address this, we have added the following sentence to the section on secondary outcome measures: “Secondary outcome measure 3, in combination with the primary outcome measures, will allow us to calculate clinically meaningful minimum differences for a sample size calculation for a full trial.”

Is a CTU being used? Please state in terms of how the randomisation will be handled (eg by independent statistician).

Response: We have added the following text to the section on randomisation: “The randomisation process will be restricted to only two of the study team (EJ and RH), one of whom is the director of the clinical trials unit for the National Perinatal Epidemiology Unit.”
A detailed statistical analysis will be performed using p-values but there is no mention of 95% confidence intervals being presented to show the (im)precision of estimates for this pilot study, or any caution given about using p-values in an underpowered study based solely on a notionally small effect size. Please address these issues briefly in the statistical methods section.'

Response: We have added the following two sentences to the statistical analysis section: “Results will be presented as point estimates accompanied by 95% confidence intervals.” and “Since this is a pilot study with a sample size based on a small effect size and unclear recruitment rates, it is not guaranteed that the study will be adequately powered to detect differences between intervention and control arms, particularly in sub-analyses.”