Author's response to reviews

Title: Effects of first exposure to plain cigarette packaging on smoking behaviour and attitudes: A randomised controlled study

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Author's response to reviews: see over
Reviewer: Ahmed Fathelrahman

Discretionary Revisions

1. On page 3, lines 42-43; there is a sentence says “the first of these studies found that the negative effects of plain cigarette packaging, such as avoidant behaviors and reduced cigarette consumption”. Avoidant behaviors and reduced cigarette consumption are not seem to be going together as they are opposite to each other. While avoidance is a negative response towards the cigarette pack, the reduction of cigarette consumption is a negative response towards the smoking behavior which means the latter is actually a positive effect if it is referring to the pack.

We thank the reviewer for this, and have reworded this sentence to avoid this contradiction.

2. On page 5, lines 96-97; it is mentioned that “randomization was stratified by sex”. I think that stratification is best fitting with sampling and data analysis and it might be better you use the term “matching”, saying “smokers in branded and plain cigarettes packs were matched by gender”. Also, is it better to use the term “gender” than “sex”?

As suggested, we have changed the wording to ‘matching’ and have replaced ‘sex’ with ‘gender’ throughout the manuscript.

3. On page 6, lines 110-111; there is a sentence saying “since they originated from different countries, packs differed in the shape, size and format”. This sentence was confusing. Please just make it “since they originated from two different countries, packs differed in the shape, size and format”.

We have made this change.

4. On page 10, lines 207-209; it is mentioned that “Finally, after participants had been shown pictures of Australian plain packs, participants were asked to report their attitudes to plain packs”. It is not clear to me what the purpose of that final step was? It was seemed to me that intervention was over by completing the questionnaires.

These questions were asked after all participants had been shown an Australian plain pack, ensuring that both those participants in the branded and plain pack condition had seen the plain packaged cigarettes. These questions were included so as to ascertain whether 24-hour exposure to plain packaging reduced smokers’ negative attitudes to packs (as have been reported elsewhere). We have included further clarification of the value of these questions in the text.

5. On page 11, lines 221-222; you mentioned that “The sample size for the study was calculated based on the primary outcome of average volume of smoke inhaled per cigarette”. I expected that it would be the average number of cigarette, why not?

Given the inelasticity of smoking behaviour, with daily smokers relatively stable with regards to the number of cigarettes they smoke per day, we hypothesised that volume of smoke inhaled would be a more sensitive measure of tobacco exposure, given that this is known to be plastic (McNeill and Munafò 2012). A reduction in this would be meaningful if continued over an extended period. We have discussed this further in the manuscript.
6. On page 13, lines 280-283 and under discussion, (after declaring no statistical differences) you said “This may be due to the relatively short trial period (with smokers using the packs for only 24 hours), a lack of statistical power to detect smaller effects that this study was designed to identify, or lack of effect of plain cigarette packaging on short-term smoking behaviour”. This style of writing causes doubt and gives an impression of uncertainty. I think it is better that you start with an explanation that you think most superior, discuss and justify it then mention other alternatives which you argued inferior. If the reason of non-significance was shortness of the trial period then exposure was not enough to produce an effect, whereas lack of statistical power means sample size was not enough and both are methodological limitations that should be discussed later on in the discussion. Remains, the lack of effect of plain packaging means that plain pack are not working and that should be the focus of the beginning section of your discussion showing how you are with or against it as an explanation of study finding.

We thank the reviewer for this comment and as suggested have moved these comments to the limitations section of the Discussion.

**Minor Essential Revisions**

1. In table 1; you did not tell what statistical test was used for testing data shown and whether there were significant differences. Yes, this is shown in results, but tables should be self-explanatory. For the variable “cigarettes smoked previous day”, please make it “number of cigarettes smoked previous day”.

We have made this change to this variable name in the table. We have not run statistical tests on the data presented in Table 1, as these describe the baseline characteristics of participants and we do not believe it is appropriate to run these tests (for a recent discussion of these issues, see de Boer et al 2015).

2. For table 2; p values indicate regression analysis, what about the means compared between the two arms of trials? What was/were the statistical test used? Also, it is not shown that data refers to the final test day.

Linear regression was used to compare the responses of participants randomised to the branded and plain pack conditions and the p values reflect the differences between these two groups. We have added further information in Table 2 to make it clearer that the data refers to the final test day.
Reviewer: Marc Willemsen

Minor Essential Revisions

1. Abstract, line 19: “increase the impact of the health warnings”. Suggestion to change this into “increase the self-perceived impact of the health warnings”(or similar wordings), as this is what was measured.

Thank you, we agree and have made this change.

2. P3., line 40. Strictly speaking, thinking about quitting and forgoing cigarettes are not a cessation behaviours, although they are associated with it. So, please rephrase.

We have rephrased this sentence and included different examples of cessation behaviours.

3. P3., line 42. “negative effects”? I found the choice of the term ‘negative’ unexpected. Avoidant behaviours and reduced consumption are positive effects (from a public health perspective).

This was also highlighted by Reviewer 1 and we have reworded this to avoid this confusion,

4. P4., line 60. The study period is 24 hours. This only allows for an assessment of the very first exposure to plain packaging in smokers. I would not call this ‘short-term’ effects (as indicated in the title), but rather something like ‘first confrontation with’. Short-term is misleading, since this term is also used in smoking cessation trials where everything shorter than 12 months is called short term, in contrast to long-term, which could be up to two years. I would strongly advice to change this throughout the manuscript.

We agree and have changed the wording to ‘first exposure to’ and have changed the title of the manuscript to ‘Effects of first exposure to plain cigarette packaging on smoking behaviour and attitudes: a randomised controlled study’.

5. P4, line 66. Reference is made to a ‘published protocol’ for more details on the procedures. This is a reference to a study (ref. 1), which does not look the same as the current study. Is this the correct reference?

Thank you for highlighting this error - the correct reference is number 13 and we have amended this in the text.

6. P4. Line 70. Why exclude smokers who want to quit smoking? And why exclude smokers older than 40? Older smokers who are interested in quitting are an important target group for health warnings on cigarette packs. The warnings might act as a cue to make a quit attempt. By excluding these groups, the study results are less generalizable to the overall population and this should be mentioned in the discussion.

We felt that it would be unethical to give smokers who wanted to quit a full pack of cigarettes to smoke. In addition, plain packaging is a population level intervention and not one targeted only at those planning on quitting. We now discuss this point explicitly in the discussion. We excluded smokers older than 40 in order to increase the homogeneity of our sample, but agree that it would have been interesting to include a wider age range. We have added a comment to this effect in the limitations section to this effect.
7. This brings me to a general comment that it is not yet sufficiently unclear what the public health relevance of the study is. Plain packs is a population measure. Surely, governments who implement this measure, expect that it will deter young people from starting to smoke and to generate more quit attempts in the general population of smokers. It would be good if the auteurs would try to discuss their findings in the context of what the policy purpose of plain packaging and health warnings might be and what the findings mean in this context. This will lead to further discussion of the limitation of the study findings, since the study is conducted among a sub-sample of the total potential target group of the intervention.

Our study provides evidence of the effect of first exposure to plain packaging on smoking behaviour and related attitudes to smoking and quitting. This first exposure acts as a precursor to later, longer-term effects on behaviour, such as quitting smoking. We agree with the reviewer that two of the key target populations for plain packaging are susceptible non-smokers and young people; however, as we were interested in the effects of plain packaging in current, regular smokers, we did not include these groups in our sample. We have discussed the policy implications further in our manuscript and discuss the limitations of the study findings.

8. Recruitment was done in Bristol, but this was not in the total population, but a convenience sample from the university? Mean age was 22, and respondents were only smoking for an average of 4-5 years. This suggests that most were students, who have little interest in quitting and do not yet perceive much problems with smoking? How many were indeed students? Please indicate. I understand that an attempt was made to also include smokers from the general population, but how many of the 128 were from that group? Did you see differences between the student population and the others? Some more details on this are needed to better understand the relevance of the study findings. In the discussion section, it should be alluded to what the restrictions of study participants mainly to students means for the generalizability of the findings and recommendations for further research.

Unfortunately we do not have data on the proportion of participants who were recruited from student vs general public populations. We have included a discussion of this in our limitations section.

9. P5, line 81. “allocated to either” (word is missing)
We have added the missing ‘to’.

10. P6., line 14. “as it was this warning” (word seems missing)
We have added the missing ‘this’.

11. P7., Details on the validity of the questionnaire are missing. What (conceptually) is measured exactly with ‘rating of cigarette pack attributes”?
These questions are taken from a previous study by (Moodie, Mackintosh et al. 2011, Moodie and Mackintosh 2013), and as described in this previous paper, measure ‘pack perceptions’.

12. Most of the items are based on previous studies by Moodie et al., but it would be good to know how the items were used in the current analyses (as composite scores or
scales?) and what the Cronbach’s #’s were. I wonder if it is OK to construct an overall score from the 8 statements about ‘changes in behaviour’. At the minimum, information on level of internal consistency of the items should be presented.

The items were used as composite scores and overall scores were calculated in the same way as in Moodie et al (2011; 2013) (measures 1-5 were used by Moodie et al (2011; 2013), whilst measures 6-8 were designed specifically for this study, although a similar format was used). Overall, there was a high level of internal consistency for each of the questionnaire measures. We have provided Cronbach’s alpha values for each measure below.

<table>
<thead>
<tr>
<th>Item</th>
<th>Cronbach’s alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience of smoking</td>
<td>0.68</td>
</tr>
<tr>
<td>Experience of using the pack</td>
<td>0.86</td>
</tr>
<tr>
<td>Rating of pack attributes</td>
<td>0.92</td>
</tr>
<tr>
<td>Rating of the health warning</td>
<td>0.79</td>
</tr>
<tr>
<td>Changes in behaviour</td>
<td>0.52</td>
</tr>
<tr>
<td>Attitudes to plain packs</td>
<td>0.71</td>
</tr>
<tr>
<td>Experience of using monitor</td>
<td>0.75</td>
</tr>
<tr>
<td>Taste test</td>
<td>0.80</td>
</tr>
</tbody>
</table>

We have now run the regression analysis on each of the questionnaire items that constitute these measures. The results of these additional analyses do not alter our conclusions. Although analyses by individual questionnaire item were presented by Moodie and colleagues (2011; 2013), we did not report this in our original manuscript as we did not specify that we would do this in our published protocol (Maynard, Leonards et al. 2014). We were also keen to limit the number of statistical tests for our main analyses. However, we now present these results as Supplementary Material.

13. P8. Four items were used to measure “Attitudes to plain packs”. However, these four items seem to measure separate beliefs about what plain packs would do to oneself (3 items) or to children (last item). Moreover, the first items is about “packaging and branding of cigarette”, while the others are about “plain packaging”. So, there are some differences between the items, which might complicate using these a one measure of attitude (again, what is the Cronbach’s #?) and question the validity of the measure as well.

First, apologies, there was a typo in our original submission: only three items constituted the ‘Attitudes to plain packs’ measure - the item about ‘packaging and branding of cigarettes’ was not included. The beta coefficients and confidence intervals for each of the three individual items are presented in the additional table described above, showing similar values for each of these items. As described above, the Cronbach’s alpha for this measure is 0.71.

14. A strength of the study was that real cigarette packs were used, where previous studies used mock packs. However, they had to ‘work’ with the Australian version of respondents’ favourite cigarettes. These might taste and ‘feel’ different to UK consumers in many ways (as is also mentioned in the discussion). This might actually reduce the ecological validity of the study, because the respondents were not confronted with a realistic intervention, but with a substitute. We cannot be sure that UK smokers
would respond in the same manner when the UK government would introduce plain packs in the future, as these 64 study participants. This could be discussed in some more detail.

We have added further discussion of this in our limitations section.

15. It is important to know if any additional data were collected which would tell us anything about whether the respondents in the exp. Group knew or suspected that the pack were imported from Australia, since the use of the Australian packs might pose a threat to the internal validity of the findings. For example, respondents in the exp. group might be curious how these ‘Aussi’ cigarettes taste, which might impact on how they assess the various psychological indicators of effect. And a more negative experience of the plain packs, might be attributed to knowing that the cigarettes in the plain pack are from abroad, and not from the plain packs and greater health warnings as such.

It is likely that participants in the plain packaging condition were aware that they were smoking cigarettes not available in the UK and this may have affected their ratings of their smoking experience, although this was not measured. However, the alternative was to use mock plain packs, which, as discussed in the manuscript, would have been of lower quality than the genuine branded UK packs. Nevertheless, we acknowledge that this is a limitation of our design, and have included a discussion of this in our limitations section.

References:


