Author's response to reviews

Title: Explaining the effects of a randomised controlled trial to implement evidence-based diabetes care: a theory-based process evaluation.

Authors:

Jillian J Francis (j.francis@abdn.ac.uk)
Martin P Eccles (Martin.Eccles@newcastle.ac.uk)
Marie Johnston (m.johnston@abdn.ac.uk)
Paula Whitty (p.m.whitty@ncl.ac.uk)
Jeremy M Grimshaw (jgrimshaw@ohri.ca)
Eileen F S Kaner (E.F.S.Kaner@newcastle.ac.uk)
Liz Smith (liz.smith@mbs.ac.uk)
Anne Walker (anne_walker@yahoo.co.uk)

Version: 2 Date: 28 September 2006

Author's response to reviews: see over
Dear Dr Mittman

RE: Revised manuscript - Explaining the effects of a randomised controlled trial to implement evidence-based diabetes care: a theory-based process evaluation.
Jillian J Francis, Martin P Eccles, Marie Johnston, Paula Whitty, Jeremy M Grimshaw, Eileen Kaner, Liz Smith, Anne Walker

Thank you for sending your and your reviewers’ comments and suggestions on this manuscript. We are pleased that the reviewers commented on either the novel combination of method and research question or the value of examining a theoretical framework to explain trial effects. We appreciate the level of detail the reviewers have offered and we believe this has helped us to write a clearer paper with a better explanation of its implications.

The table below lists the editor’s and reviewers’ suggestions, our response to each, and the relevant page number in the revised manuscript.

<table>
<thead>
<tr>
<th>Suggestion</th>
<th>Response</th>
<th>Page ref (revised m/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Editor</strong></td>
<td></td>
<td></td>
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<tr>
<td>1. Formatting of reference list</td>
<td>We have re-formatted the citations and reference list using Refworks.</td>
<td>19-20</td>
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<tr>
<td>2. Define key specialised terms</td>
<td>We have defined the following terms in the note to Figure 1 and also in brackets, following first use of each term: attitude, subjective norm, perceived behavioural control. We explain direct and indirect measurement in the method section and ‘attitudinally-driven’ and ‘normatively-driven’ when they first arise in the Results section.</td>
<td>6</td>
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<td><strong>Reviewer 1: Discretionary revisions</strong></td>
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<td>3. Provide more detail on questions used, to allow replication.</td>
<td>The full questionnaire has been attached as a separate file.</td>
<td>Attached.</td>
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<tr>
<td>4. Provide more detail about the scoring method, especially with respect to the multiple composite approach, and justify the use of a 1-7 response scale.</td>
<td>We have provided brief detail but we feel that any further elaboration would be too detailed for this readership.</td>
<td>7</td>
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<td>5. Report the design of the MANOVAs.</td>
<td>We have done this.</td>
<td>8</td>
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<tr>
<td>6. Justify the use of both direct and indirect measures in the same analysis and report results.</td>
<td>We have provided a justification and reported the one significant 2nd-step finding out of the six hierarchical regressions performed.</td>
<td>6, 9</td>
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<td>7. Present analyses that highlight effects of demographics e.g. practice size, professional group at 1st step, TPB variables at 2nd step.</td>
<td>We have reported this additional analysis briefly, indicating that the pattern of prediction of TPB variables is unchanged after controlling for practice size and professional group.</td>
<td>9</td>
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<td>8. Page 10: Insert % after 64</td>
<td>We have now reworded the explanation of Table 4 results and deleted this sentence.</td>
<td>-</td>
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<td>9. Page 11: Briefly discuss difference between and relative usefulness of descriptive and injunctive norms.</td>
<td>We would relish the opportunity to do this, but in the light of Reviewer 2’s comments about jargon we think that this level of technical and theoretical discussion is not appropriate for this readership. We would welcome further advice on this point.</td>
<td>-</td>
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<td>10. Conclusions: Discuss the possible influence of practice size on PBC.</td>
<td>There was no influence of practice size on PBC and, for clarity on this point, we have added a sentence at the end of the report on the MANOVAs.</td>
<td>9</td>
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<tr>
<td>11. Table 4: Clarify and provide more explanation and comment on these results.</td>
<td>We have explained Table 4 in more detail and we have included the direction of coding of the trial groups below Table 4. We thank Reviewer 1 for drawing our attention to the lack of clarity here.</td>
<td>9-10</td>
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<tr>
<td>12. Compare TPB scores for intervention and control groups.</td>
<td>We believe we reported this by reporting the (lack of) main effects in the aforementioned MANOVAs. However, the point is taken that we have not made this result clear enough and we have added a sentence to improve clarity.</td>
<td>9</td>
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</table>

**Reviewer 2: Concerns**

13. Change text that assumes a direction of causality (i.e. 'predict'), because the behaviour had been changed before attitudes were measured.  
First, we did not purport to predict behaviour, merely to predict intention (for three trial outcomes that are logically related to behaviour). We have tried to express this more clearly. Second, we distinguish between prediction (i.e. something we as researchers do when we know one score e.g. attitude and want to estimate another e.g. intention) and causation (i.e. when one factor is brought about by another, independently of whether the factors are measured). But we acknowledge that this is quite a fine distinction in practice. We have explained this distinction and have used the term 'prediction' carefully thereafter.  
4 |

14. Clarify assumption that attitudes were the same in both groups before the intervention.  
We have already made the point about assumed equivalence of the groups at baseline in the ‘Limitations’ section.  
12 |

15. Define key terms; reduce jargon; write in active voice.  
We have reduced the use of passive voice throughout. Also see Point 2.  
Various |

16. Define direct and indirect measurement and explain the different assumptions behind each.  
We have done this.  
6 |

17. Possibly delete Tables 2 and 3 and report coefficient alphas in text.  
We have eliminated Table 2 and now report the main features of the patterns of coefficient alpha in the text. But as we have taken the reviewer’s advice to provide the questionnaire we now feel that the  
9 |
correlation and descriptive statistics would be helpful to readers to interpret the study. So we have retained Table 3 (now numbered 2).

18. Possibly some questionnaire items are redundant across scales. Perhaps do a multi trait scaling to check this.

As the reviewer commented, the paper is not about scale formation. We feel that reporting on multi trait scaling would detract from the main message of the paper. But we agree that it would be useful to provide more explanation to the effect that we followed ‘standard’ methods for operationalising these constructs, methods that are recommended in this field.

In addition, during the course of revising the manuscript we changed the following:

- We have altered the title to make it clear that this process evaluation is linked to a separately reported trial.
- On page 4, where we clarify that this study investigates intention rather than behaviour, we justify this approach by citing a systematic review of the intention-behaviour relationship (Eccles et al.), currently in press with Implementation Science.
- On page 4, we reported brief trial results for two of the three behaviours investigated in the process evaluation study. We added the result relating to the third behaviour, measuring blood pressure.

We are also aware that your journal is currently considering the paper describing the main trial that is related to this study. The authors of that paper (some of whom are in common with this paper) will be submitting a revised manuscript in response to reviewers’ comments in early October. If you decide that both revised papers are acceptable you may consider it suitable to publish the two papers together. If so we would be happy if the publication of the current paper is delayed to fit a timeline appropriate to this strategy. We appreciate there are a series of “ifs” in this sequence but felt it important not to let the potential opportunity pass by unconsidered.

We thank you for the opportunity to revise and resubmit this manuscript. We hope these changes satisfactorily address your concerns and those of the reviewers and look forward to your further comment.

Yours sincerely

Jill Francis and co-authors.