Author's response to reviews

Title: Normalization Process Theory: a framework for developing, evaluating and implementing complex interventions.

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Author's response to reviews: see over
Response to reviewers’ comments.

<table>
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<th>Reviewer 1.</th>
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| **Abstract** | We have expanded the sentence in the abstract background as suggested by the reviewer, so that it now reads: “Such interventions can only have a significant impact on health and health care if they are shown to be effective when tested, are capable of being widely implemented and can be normalised into routine practice.”

Abstract Summary has also been amended in line with the reviewer’s comments, so that the first sentence now reads: “The NPT is a new theory which offers trialists a consistent framework that can be used to describe, assess and enhance implementation potential.”

We agree with the referee that all trials are themselves complex interventions and have expanded both the abstract and the text of the main paper to reflect this: “The need to ensure trial procedures are feasible and compatible with clinical practice is not limited to trials of complex interventions and NPT may improve trial design by highlighting potential problems with recruitment or data collection, as well as ensuring the intervention has good implementation potential.” |

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<th><strong>Background.</strong></th>
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<td><strong>Old Paragraph 2:</strong></td>
<td>We have expanded our argument in paragraph 2, page 4, both in relation to patient recruitment and the wider issues of the gap between research evidence and practice. In both cases, we have strengthened the link between the gaps identified and the potential solutions offered by NPT.</td>
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**Old Paragraph 3:** | It is our contention that both researchers designing complex interventions and funders funding their evaluation should consider using NPT to assess an intervention’s potential for implementation success. We have therefore expanded this paragraph, on pages 4-5, to make this clearer. |

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<td><strong>Use of NPT to define context:</strong></td>
<td>We have expanded Section 2.1.1, page 6, detailing how use of NPT helped us to understand the context in which a complex intervention was set and adapt the intervention to increase its use in primary care. We have also expanded Section 2.1.3, page 6, to show how lessons derived from using NPT in the Impact Back study were then applied to the design of a subsequent complex intervention.</td>
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**NPT in relation to clinical trials:** | We have now expanded our discussion of NPT as a trial killer to consider clinical trials as well (page 7). |
### Implementation:
We accept that there is a wide literature on the issues of implementation. We have expanded our discussion of that in Section 1.1, with particular reference to the needs of policy makers, and refer to that in this Section on page 8.

### Summary.
**How does this approach build on that of others?**
We have expanded our argument explaining why we believe that NPT develops the issues discussed in this paper – see pages 8-9.

### Discussion
We have expanded the last sentences to address the comments of the reviewer.

### Reviewer 2.
**Section 2.1:**
In Section 2.1.1, page 6, we have expanded our discussion of the way in which understanding the context is important and how context may impact on the four components of NPT, namely coherence, cognitive participation, collective action and reflexive monitoring. We have also expanded Section 2.2.1, page 7, to further address this criticism.

Later, in Section 2.3.1 page 6, we have expanded on the way in which the information was translated into action, in relation to both the re-design of the Impact Back study and the development of a later trial.

**Strengths and limitations of applying NPT:**
We expanded our discussion of the issue surrounding implementation in Section 1.1, with particular reference to the needs of policy makers. We have also expanded the Summary and relating our work on using NPT with the recent Cochrane review on tailored interventions, as helpfully suggested by the reviewer.

### Abstract.
This has now been expanded.