Reviewer's report

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

Version: 1 Date: 11 June 2010

Reviewer: Aloysius Niroshan Siriwardena

Reviewer's report:

The authors address three areas that are of definite interest to researchers involved in design and evaluation of complex interventions, using Normalization Process Theory (NPT) as a framework.

The first issue is the argument that NPT can inform the initial design and development of complex interventions in such a way that they are more likely to be adopted and 'normalised'. The second issue relates to use of NPT to improve trial design. The third is around spread of interventions shown to be effective. I enjoyed reading this paper and feel that the subject area is important – but trying to cover these areas in a single discussion paper was problematic for me – each issue has an extensive literature, each a different context and the gaps in the literature are overlapping but different.

Abstract

Background: - The following sentence needs clarification: “Such interventions can only have a significant impact on health and health care if they can be widely implemented.” I understand that complex interventions are more likely to be implemented if they can be normalised into practice and that NPT can help design complex interventions which are more likely to be normalised. However, significant impact on health and healthcare depends on the complex intervention being effective (and cost-effective). There are complex interventions which can be normalised but ineffective and inefficient when tested in a clinical trial and others, as the authors state later, which can be shown to be effective in the context of a trial but incapable of wider implementation. Therefore, it might be better to say that such interventions can only have a significant impact on health if they are designed to be normalised, capable of wider implementation and shown to be effective and efficient when tested.

Two sentences in the discussion were confusing to me.

“The NPT is a new theory which offers trialists a consistent framework that can be used to describe and judge implementation potential.” In the paper the authors argue for using NPT to design and improve the complex intervention rather than just simply to describe and judge (assess) it.

“We encourage trialists to consider using it in their next trial.” Presumably, this suggestion relates to design and modelling of complex interventions; however,
since all clinical trials are themselves ‘complex interventions’ this could refer to all rather than just trials of complex intervention.

Background

I think the second paragraph needs expanding from the following sentence, “Notably recruitment to trials remains problematic[10] and the gap between research evidence and practice remains wide [11]”, to add more explanation as to why these problems continue, what the gaps are and how why the author’s approach is different.

It is not clear which the authors are arguing that funding bodies should use NPT to assess allocation of funding or whether researchers should use NPT to decide how to use their time, or both in relation to the following: “The research community needs some way of considering the likelihood of implementation success when allocating scarce research resources to trials of complex interventions.”

Discussion

Use of NPT to develop a complex intervention. The authors argue that NPT can be used to define the context and the intervention and assess its impact. The example they give is of a post-hoc assessment although there is an implication that NPT can be used as a framework to develop better interventions. It would therefore also be helpful to cite an example where the design has been informed by NPT or where it has been changed because of a NPT assessment prior to exploratory or definitive testing.

Use of NPT to optimise evaluation of a complex intervention. It would be helpful if the authors could discuss whether NPT can be used to optimise the design of any clinical trial rather than just a complex intervention trial.

Implementation. This is an important area with an extensive literature but the description in the paper was brief and could be expanded.

Summary

It would help to describe how the author’s approach builds on or is different from other ways of addressing the three issues raised in this paper.

Which journal?: Appropriate or potentially appropriate for BMC Medicine: an article of importance in its field

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a
statistician.

Declaration of competing interests:

I declare that I have no competing interests.