Reviewer's report

Title: Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting

Version: 1 Date: 3 September 2012

Reviewer: Ann Louise Kinmonth

Reviewer's report:

This paper proposes a framework for the design and reporting of process evaluations within cluster randomised trials of complex interventions. It is thus focusing on a sub group of complex intervention trials where the unit of randomisation is not the unit of analysis.

In cluster randomization trials, numbers of groups of individuals are randomized to receive different interventions; the units of randomization for such trials are diverse, including, for example, clinics, hospitals, worksites, and entire communities. A key issue is that in these trials the effect size is inferred at individual level, allowing for similarities of individuals within clusters by estimation of a “design effect” Little of this is described in the context section.

The background provides definitions of process evaluation (studies which run parallel to or follow a complex intervention trial to understand the trial processes or underlying mechanisms in relation to context, setting, professionals and patients.) They make the important distinction between understanding of causal links between intervention and outcome and informing implementation.

They do not clearly differentiate between trial delivery and intervention delivery within the trial design.

The methods include selective review of the literature, with the motivation to design a new trial of an intervention to improve prescribing safety, and discussions among the authors tested against published evaluations. A focus was chosen on purpose, design and reporting.

Findings They found that process evaluation is a broad umbrella term that tells little about the purposes or methods used. They highlight the lack of quantitative approaches to process evaluation.

Their examples of process evaluations include recruitment rates and patient adherence to therapy. These might be considered to be belonging to quite different domains; one is an example of the successful realization of the trial delivery, and the second relates to the successful realization of the intervention delivery. Both may affect the interpretation of the trial and the effective delivery of the intervention in a broader context.

They found no clear approach to reporting of studies.

Framework.

The Framework proposed defines processes involving clusters and those
involving the target population. I could not quite understand the levels here; it seems to depend on an assumption that there are only two levels in the design; viz the unit of randomisation (the cluster) and the unit of measurement (the individual within the cluster) But what if PCTs were to offer training to practice leads to work with key workers to reduce child abuse in practices? In the trial, the cluster could be key workers or practices perhaps, and the population of children in a practice or attached to a key worker could be the cluster size, with outcome as a measure of abuse? I could not quite map this to the framework and would I use path analysis or some other multilevel approach to consider where the enablers and blocks to intervention delivery and receipt might be?

The Framework (fig 1) considers recruitment of and intervention delivery to and adoption by clusters (not participants) and reach to participants (receipt?) and delivery to participants (how does this differ from reach?) and response (not defined?) as well as issues of maintenance and intended and unintended outcomes (should harm be specified in the table?)

In a Table, these domains are linked to research questions and methods and stage of data collection advised. The use of the word cluster as if it were an actor rather than a group of participants is rather confusing; how can a cluster agree? (This question underlies much of the ethical discussion about cluster trials) How can a cluster deliver an intervention? And to whom? What is a cluster member here the doer or the done to? The unit of randomisation or the unit of measurement? And so on down the table.

The methods recommended are quantitative and qualitative and mixed methods. There is a brief consideration of theoretically driven interventions, sociological methods to guide adoption, and of pragmatic models, but the essential difference between these being a-priori or post hoc and exploratory; between testing a proposed mechanism and discovering a new one is not clearly made. In this section

Proposals for reporting; a series of sensible proposals are made for reporting which are exemplified in Table 2 with selected studies; there is a lack of quality assessments and of substantive findings. It was unclear why these exemplar studies were chosen

The concluding recommendations are sensible, but issues of validity might perhaps be enhanced by consideration of quality and not just quantity of processes reported.

1. Is the question posed by the authors new and well defined?

There is no clear question. The aim is to propose a framework for process evaluations for cluster randomised trials in terms of design and reporting. The need is well justified in the background.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work? We would need clearer descriptions of the search protocol and analysis of papers, and of selection of papers to meet this criteria; it is presented as an essentially descriptive method; The literature list includes examples of most of the seminal papers I know, but not an extensive list of
cluster trials, and the reason for choosing the examples cited in the background are unclear, as is why they exemplify the type of trial referred to.

3. Are the data sound and well controlled?

No data presented

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

Not relevant for a descriptive piece?

5. Are the discussion and conclusions well balanced and adequately supported by the data?

Alternative approaches to understanding how the trial has been conducted, how the intervention has been applied, whether proposed mechanisms of trial action are supported in the data, and how best to implement the findings in a different (wider) population would be helpful; the paper is quite short and would be more authoritative if longer with stronger methods and critique

6. Do the title and abstract accurately convey what has been found?

There is a bit of wandering towards all trials of complex intervention rather than cluster randomised trials and the word cluster does not seem to appear in the abstract but otherwise yes.

7. Is the writing acceptable? The writing is fine, except for the confusion over the use of the word clustering.

- Major Compulsory Revisions

1. Add details of the literature searches used to inform the Framework and divide them into trial specific, systematic reviews and overviews and policy recommendations

2. Present a summary of the studies found and explain why you selected from these the studies presented in the paper

3. Define clustering clearly throughout; to me recruitment of a cluster refers to the recruitment of all individuals in one of n groups on whom the principal outcome is measured and not as used in the Framework to the level of the randomisation? Similarly under Response, to me how clusters deliver the intervention is impossibility since the clusters include those to whom it is to be delivered. So it would help to refer to its relationship to statistical techniques for randomisation perhaps Donners seminal work;


4. Discuss the other approaches in the literature more fully and explain more clearly where your framework improves on them; egg the MRC documents and the Re-Aim approach, and the Implementation research approaches are documented but their strengths and limitations are not so clear. The relevance of multi-level analyses is not considered. Our own approach was defined by the consideration of behavioural determinants and cognitive and clinical processes (see Hardeman W, Sutton S, Griffin S, Johnston M, White AJ, Wareham NJ, Kinmonth AL (2005). A causal modelling approach to the development of
theory-based behaviour change programmes for trial evaluation.

Health Education Research, 20, 6, 676-687.) The point is to make crystal clear how the framework incorporates or adds to these published approaches.

5. Discuss issues of quality assessments of process evaluations

The author must respond to these before a decision on publication can be reached. For example, additional necessary experiments or controls, statistical mistakes, errors in interpretation.

- Discretionary Revisions

1 Abstract; should the word cluster appear in the abstract? Should you mention your own trial here and the case based motivation underlying the paper? Could you put in your nice results rather than saying you believe they will be useful to others? Eg different approaches to understanding trial delivery, intervention delivery and receipt, investigating hypothesised mechanisms, proposing mechanisms and implementation studies

2. Reach in target populations; would it help to add to how representative they are of the population for implementation?

3. I am not sure you are making enough of your conceptual grasp; Could the paper perhaps benefit from dividing the key processes into those of trial delivery, of intervention delivery, and of implementation in the wider population; this leads one to consider for example duration and maintenance in the trial since we don’t want to spend money of implementation of an intervention which is only short term effective etc.?

Level of interest: An article whose findings are important to those with closely related research interests

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.