Reviewer's report

Title: Evaluating complex health interventions: a critical analysis of the 'outcomes' concept

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Reviewer: Andrew Long

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The article presents an interesting piece for debate and presents a conceptual model to help take thinking further forward. The issue is of significance not just within research on CAM, but to complex interventions in general.

I have three main questions in relation to the argument and would suggest that the authors consider and take on board these comments in revision of the article (i.e. major compulsory revisions):

Firstly, while accepting and supporting much of the argument the authors make about the need and importance of broadening our interpretation and use of the outcome’s concept and what is measured, I feel that some of the assumptions that the authors suggest lie within the concept are not within it per se, but derived and associated with the way it has been used in research, and in particular, the RCT paradigm. Looking back to such writers as John Stuart Mill, in relation to causality, an outcome is an end-result of antecedent event (or events). These occur in particular contexts etc. The point I am trying to make is thus that, within the RCT, yes, a linear assumption (of causality => outcome) is made; other approaches, such as programme theory and even technical statistical processes (e.g. statistical modelling), allow / encourage exploration of different causality assumptions or models.

I thus would suggest that, while depicting their article as not being focused on the issue of the RCT, it is indeed so situated. More generally, its focus lies on the issue of appropriate research designs informed by appropriate conceptual frameworks, that is, a more theory-oriented approach to research. I don’t think there is anything inappropriate about this; I do think that the authors should say that this is what they are doing, as this would strengthen their argument and the readership of the article. What I am suggesting would involve modifying the way they talk about the assumptions to address this core issue.

Secondly, I like the suggestion of use of programme theory (logic modelling in the North American context – perhaps worth pointing to!). But it is not alone. In the long established field of quality assurance, think back to the classic Donabedian conception of quality as effected by structure (cf. general context), process (cf. intervention in a particular context) and outcome. It might be worth adding this point within the discussion.

Thirdly, their IPCOE framework is interesting. Its presentation reinforces the first
comment that I make above. Focus lies on the way we think about the whole research, not just the ‘outcomes’ component. If the primary focus lies on outcomes itself, then I would have anticipated a more detailed exploration of the contrasting notions ‘outcomes’ and ‘experiences’, and different meanings attached to these. For example, some use the term ‘experience’ to relate to ‘feelings about what happened within the intervention’ (itself an outcome, but not a ‘final’ outcome).

Some other points (all minor essential):

• Background (p3 line 7): Indicators, measures and outcomes. Strictly an indicator is not an outcome, it can only be an indicator of an outcome (cf. discussions on measurement – direct and indirect (indicator) measures). It would here or later be worth acknowledging that the concept of outcome has a long history (predating pharmaceutical research!).

• Page 11, 3 lines from bottom: elaboration of the content of Box 2 is appropriate (what should the reader be seeing / taking away from this). And in relation to Box 3, an example of context effects (I thought perhaps wrongly), it is important to spell out what is meant by context (though maybe the reference is to assumption 3). My confusion illustrates the point, that it is important to make it clear how the boxes illustrate the two assumptions being talked about. So in 2nd para on p12, spelling out the ‘context’ elements would be valuable.

• Page 16, end of first para: it is important to clarify the meaning of the phrases in quotes. This is interesting and needs expanding.

Level of interest: An article of importance in its field

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.