Reviewer's report

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

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Reviewer: Carl May

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This is an interesting and well written paper that argues against a pharmacological ‘outcomes’ model for complex interventions research like that outlined in the 2001 MRC Framework [1, 2]. The authors are not the first to argue that experiential effects are also important, or that ‘objective’ outcomes raise epistemological problems that are elided in the literature of randomised controlled trials. They do present, however, a powerfully framed set of ideal-type assumptions that run through that literature and which neatly convey some of the conventions of designing and reporting outcomes studies, comparing (p9) conventional and complementary therapies for RA.

‘Outcomes’ in conventional therapies are the measurable products of a set of causal mechanisms that have been already demonstrated to exist and which are, in broad terms, usually well understood. This is not necessary true of some complementary or ‘alternative’ treatments, in which comparable mechanisms are sometimes either not demonstrated to exist or believed to be understandable in the same way. So it stands to reason that a different way of conceptualising outcomes, in which experiences and processes matter as much as objective endpoints, would be of value to complementary healthcare. This critique is important, and is certainly not restricted to complementary therapies.

Where I part company with the authors is in recommending programme theory as an over-arching conceptual framework for working towards understanding processes. The linking argument needs to be much stronger to carry this off (this is a compulsory revision). Also, it would be good to see more in the way of convincing evidence for the benefits of this model. In relation to this, it will be important to also take account of the recent shifts in the MRC framework [3] and the many other models for process evaluation in trials (e.g. Re-AIM [4]) that do not focus on ‘pharmaceutical’ outcomes in the way that they claim (this is a compulsory revision).


**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’