Reviewer's report

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

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Reviewer: Claudia Witt

Reviewer's report:

The paper by Paterson et.al addresses a relevant and highly interesting topic. It is well written and considers the relevant literature.

Major Compulsory Revisions:
The concept of outcomes as used here seems to represent a more conservative approach. For a reader who is familiar with the discussion about the concepts 'efficacy' and 'effectiveness' some of the assumptions in this paper might not seem to reflect recent changes in clinical non pharmaceutical research methods. In effectiveness studies on non pharmaceutical more and more patient centered outcomes got acceptance. Especially for pain diseases mainly subjective patient reported outcomes are used as primary parameters. Assuming the outcomes concept as used here reflects mainly those of conventional drug trials, I suggest to clarify this in the paper, e.g., by using the term “clinical drug trials” instead of “clinical trials”.

Minor Essential Revisions:
Title: Please specify the outcome concept in the title
Background: The categories of outcomes should be included (subjective vs. objective, disease specific vs. general outcomes such as overall quality of life)
Background: Please include the aspect of so called “outcome” research (or outcome studies) from health service research to avoid misunderstanding.
Page 7: Please provide some information about the methods which were used to identify the 8 assumptions.
Page 9: Please give a short example for a complex intervention.
Page 16: Programme theory: It would be helpful to know whether this has been applied to complex conventional health service research and in which research field this method is accepted.
Conclusions: Could the development of new quantitative measurement instruments (which assess changes in awareness and new competences) be one result from qualitative work on this topic?

Typos:
Abstract: last sentence of methods: delete one “.”
Page 9: The applicability of.........4 th line of: delete one “.”
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