

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	What can qualitative research do for randomised controlled trials? A systematic mapping review
AUTHORS	O'Cathain, Alicia; Thomas, Kate; Drabble, Sarah; Rudolph, Anne; Hewison, Jenny

VERSION 1 - REVIEW

REVIEWER	Dr Maggie Lawrence Senior Research Fellow Glasgow Caledonian University Glasgow, G4 0BA, UK
REVIEW RETURNED	02-Apr-2013

GENERAL COMMENTS	<p>Peer review comments</p> <p>This paper was a pleasure to read. It is well written and well structured. It presents a clear and transparent account of the methods involved in the review process. It is on topic of interest to those interested in the development and implementation of review methods and is of interest to researchers developing complex interventions. There is useful learning for interventionists to be had from this paper – I hope trialists take note!</p> <p>I have no suggestions for changes or amendments; however, I do have some comments around the theoretical approach to evidence synthesis and translation into practice. Effectiveness is discussed throughout the paper, where reviewers such as myself, might have distinguished between feasibility, acceptability, meaningfulness and effectiveness (FAME) – I realise these terms are used to an extent. I wonder if the reviewers are aware of the work by Professor Pearson and colleagues at the Joanna Briggs Institute in Adelaide, Australia. It strikes me that Pearsons' work on the FAME framework is of relevance to the reviewers' work, although it may reflect a theoretical perspective regarding the analysis and presentation of evidence than that of the reviewers, which is why I do not suggest incorporating it into this paper.</p> <p>Refs: Pearson A. (2004) Balancing the evidence: incorporating the synthesis of qualitative data into systematic reviews. <i>JBI Reports</i> 2, 45–64. Pearson A., Wiechula R., Court A. & Lockwood C. (2005) The JBI model of evidence-based healthcare. <i>International Journal of Evidence-based Healthcare</i> 3, 207–16.</p>
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REVIEWER	Karen Daniels, Specialist Scientist, Medical Research Council of South Africa
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	I declare that I have no competing interests.
REVIEW RETURNED	08-Apr-2013

RESULTS & CONCLUSIONS	They're discussed in the light of previous literature which has been mainly theoretical rather than empirical.
GENERAL COMMENTS	<p>I found this to be an excellent piece of work! It is extremely relevant to the debates on how strengthen the evaluation of health care interventions. This study makes an important contribution to our understanding of the use of qualitative research alongside randomised controlled trials within this field. My comments thus are minor.</p> <p>Keywords: I wasn't sure if the authors were limited in having to use standardised keywords prescribed by the journal? None the less, I found the keyword "statistics" and "therapeutics" did not seem to be appropriate. It was also my understanding that the authors looked at all randomised controlled trials and not just "clinical trials", thus I think that this keyword should be expanded to "randomised controlled trails".</p> <p>Background: There is more than one Medical Research Council internationally. Thus the authors need to make clear that they refer to the Medical Research Council of the United Kingdom.</p> <p>Methods general comment: It would be useful to add the time span it took to conduct the review, particularly the time it took to do the screening, framework development and data extraction. This would give other authors contemplating such a review an idea as to how much effort might be required. I think it would also give further weight to the enormity of the task.</p> <p>Methods, paragraph one: The authors need to explain more clearly what they mean when they say that they reviewed published articles "because these are accessible to individuals making use of evidence of effectiveness". With the trend of dumping everything on the internet, and the cost of non open access articles, grey literature may be as accessible and sometimes more accessible. Perhaps leave the explanation out, since reviewers are within their rights to make decisions around how they will limit their search. Alternatively the authors might prefer to say that published articles offer more guarantee of ensuring robust evidence since they are subject to the process of peer review.</p> <p>The search strategy: I feel that Figure 1 should be summarised into narrative form and included as an appendix rather than as part of the main text. Reading a table that uses search code, such as dollar signs, doesn't help the general reader to better understand what you were looking for. But if the table is moved to an appendix then those readers who might want to either repeat your search or otherwise check its quality, will still be afforded this opportunity.</p> <p>In my understanding EndNote is reference management software, rather than data management software, in that one uses it to organise references and not data. In the Thompson Reuters own words, "EndNote is the industry standard software tool for</p>

publishing and managing bibliographies, citations and references". Calling it data management software makes it sound like you used a statistical programme or a text analysis programme.

Inclusion and exclusion criteria:

The sentence "These could include qualitative ... mixed methods article" may be clearer if expanded. I would suggest "These could include qualitative research published as a standalone article or reported within a mixed method article".

Screening references and abstracts:

I don't understand what the authors mean when they say they "applied the exclusion criteria electronically". Did you run searches within Endnote and exclude references on this basis? The alternative is that you're referring to the further refinement of your search strategy, which would have reduced the number of records. That in my opinion is not the same as exclusion, since it is done by the information specialist albeit in consultation with the reviewers.

I think that the authors should exclude the sentence "The rationale was that ... for future practice". To me that sentence feels like an over justification, and has the adverse effect of making it sound like the authors were cherry picking. Anyone who has ever attempted a review would understand that you took on an enormous task and that you would have had to make some hard decisions about cut-offs. The authors could simply, if they want to, end the previous sentence by saying that this literature was the most contemporary. But I really don't think that the justification is needed. On the other hand, by keeping the argument that these articles would "offer the most useful insights for future practice", the authors open themselves to being criticised for saying that older articles are less useful, which is not necessarily true.

Data extraction:

I don't know if I am misreading the manuscript, but I don't understand how the authors came to choose only six articles within each sub-category for "formal data extraction"? Why was data not extracted from all 296 articles? How did the authors choose which six articles to look at per sub-category? Also it gets a bit confusing when the Results report on 296 articles rather than 104, implying that all articles were extracted. Where there perhaps two different kinds of data extraction, formal and other?

Size of the evidence base:

It would be good to know how many trials the 296 articles were linked to. I've worked on qualitative studies alongside two big trials. In both cases we had several qualitative papers but only one trial paper.

Summary of findings:

This is just an observation – I've had the experience where previous qualitative work in the geographical and content context have influenced the design on a trial, particularly the design of the intervention being trialled. This qualitative work was however not done in relation to the trial, but still it was part of the building blocks. I'm sure that this happens often, but I am equally sure that it would be very hard for anyone outside of the trial research team to be able to make the link.

Strengths, weaknesses and reflexivity:

	<p>It is a limitation that only English language articles were used.</p> <p>Implications: Should it be “open to emergency issues” or “emerging issues”?</p>
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REVIEWER	<p>Dr Nicola Mills Research Fellow University of Bristol UK No competing interests</p>
REVIEW RETURNED	09-Apr-2013

GENERAL COMMENTS	<p>This is a novel and insightful piece of research mapping out how qualitative research is used with RCTs. The search strategy is comprehensive and the exclusion/inclusion criteria are explicit and justified. The results are well presented and sufficient examples have been given to support categorisations. The authors are aware of the main limitations. A fascinating read!</p> <p>Typo on p20, line 44 - drop "limited"</p>
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VERSION 1 – AUTHOR RESPONSE

M Lawrence review:

We had not heard of FAME and found it a very interesting read. We agree that adding it into the paper will not be helpful but it will help our wider study.

N Mills review:

We have corrected the typo.

K Daniels review:

1. We agree that the keywords are inappropriate but they are the best ones we could choose from the selection given by the journal. We have asked the editor if we can use different ones.
2. We have changed the MRC to the UK MRC.
3. We have included the timeframe for the review. It was a major undertaking and you are right – we need to let people know this in case they wish to embark on a similar exercise.
4. We have removed the sentence justifying inclusion of published work only.
5. We have made Figure 1 into an appendix.
6. You are right about Endnote and we have changed this.
7. We have used your version of the description because it is much better.
8. We have clarified that the electronic search was searches in Endnote.
9. We have removed the sentence justifying the choice of the later time period.
10. We have clarified that the framework was based on reading all 296 abstracts and articles and that detailed data extraction was undertaken on 104 articles only. We also describe how we selected six

articles in each sub-category.

11. We simply do not know how many trials these articles are linked to. We definitely came across more than one article from a single trial.

12. We undertook some interviews with researchers as part of the wider study and some of them echoed what you say here about using learning for the next trial undertaken by the same team. We have added a few words to take this into consideration.

13. We have included the extra limitation about English language papers only.

14. We have corrected the typo 'emergency'.

VERSION 2 – REVIEW

REVIEWER	Karen Daniels Specialist Scientist Medical Research Council of South Africa South Africa I declare that I have no known competing interests.
REVIEW RETURNED	29-Apr-2013

GENERAL COMMENTS	<p>I am happy with the changes and believe that the article is now ready for publication. I have one suggestion for clarity, and one response to the authors.</p> <p>For clarity: I think that the explanation “although in the large intervention sub-categories we selected six which showed the diversity of content of the sub-category” would be more clear if phrased this way “... although in the large intervention we <u>purposefully</u> selected six studies <u>so as to show</u> the diversity of content <u>of/in</u> the sub-category.” If my changes do not indicate what you meant, then you need to add your own clarification because the difference between this and the random selection is otherwise unclear.</p> <p>Editors: This is a discretionary comment, I don't need to see the revision.</p> <p>Response to authors: Authors response: “11. We simply do not know how many trials these articles are linked to. We definitely came across more than one article from a single trial.” My response: I wasn't really clear enough in my articulation of the initial comment. I was really interested for my own sake to know if you had more than one qualitative study in the review, that was attached to the same trial. But as I said, this is my interest, and therefore not something that adds to your paper, so no need to respond further.</p> <p>I look forward to seeing it in print!</p>
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