

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)	Quality of descriptions of treatments: A review of published randomised controlled trials
AUTHORS	Schroter, Sara ; Glasziou, Paul; Heneghan, Carl

VERSION 1 - REVIEW

REVIEWER	Matthew Sydes Senior Statistician MRC Clinical Trials Unit London UK I have no competing interests to declare
REVIEW RETURNED	03-Sep-2012

GENERAL COMMENTS	<p>Major points</p> <p>:: Need to justify in the text why 2006 was chosen and why only this year as it really limits the sample size and seems old: much might have changed since then.</p> <p>:: Need to justify in the text why just BMJ was used. Was it about access to editors' notes? This might be good reason (but makes the lack of years more bothersome).</p> <p>:: If results are to be translated into practice, would there be research guidelines developed? Is the primary publication the best source of information to describe the treatment? If the treatment is to be used elsewhere, would researchers/practitioners not contact the original researchers? Would publication of protocol help?</p> <p>:: A CONSORT extension is referenced. Is this already in play and do people use this? Was it in 2006?</p> <p>:: The paper only talks about papers that were chosen for publication in BMJ. What of those that weren't? Were any rejected only because the description of treatments had been inadequate?</p> <p>Other points</p> <p>:: It is concerning that papers were seen as inadequate even when problems were highlighted to authors prior to publication</p> <p>:: What is "no constraints" in Figure 2?</p> <p>:: Intro: is it fair to describe homeopathy as a treatment? Probably not.</p> <p>:: Whose fault is missing data? Author, reviewer, editor? Seems that</p>
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	<p>reviewers commonly asked for information that wasn't provided in the final paper.</p> <p>:: Checklist seems to be compared to CONSORT. Is the development process similar? It seems that CONSORT is an internationally developed consensus of points, but the checklist is the work of but three people.</p> <p>:: Where all points in the checklist relevant to all studies? If not, how was this accounted for in the % provided?</p> <p>:: "For each checklist item the proportion of adequately described features ranged from 47% to 94%" I misunderstood at first that this was % of studies for a given checkpoint rather than the % of points for a given study. Perhaps this could be clearer?</p> <p>:: Production quality of figures 1 and 2 is low.</p>
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REVIEWER	Dr Steve George Reader in Public Health University of Southampton Faculty of Medicine
REVIEW RETURNED	13-Sep-2012

GENERAL COMMENTS	<p>This is an interesting paper that addresses an important question, and one which, anecdotally at least, is familiar to triallists. The methods are simple and clearly described, and the only potential failing of the paper is that the journal from which the authors selected their trials, the BMJ, is a leading medical journal and will have papers which are of substantially better quality than those in other journals, but the authors draw attention to this in their discussion and it doesn't pose a barrier to publication. Other than that there is a need to check punctuation in some places but this is a minor issue. I recommend publication of this paper.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: Matthew Sydes

1) Need to justify in the text why 2006 was chosen and why only this year as it really limits the sample size and seems old: much might have changed since then.

Comment: The research was conducted in 2007 and we have been tardy at publishing it. We already acknowledge in the text that the situation may have changed since 2006.

"..... we evaluated RCTs published in 2006 and it is possible that there have been improvements in reporting, given the wider use of the internet and web appendices in recent years."

Change: We have added a Settings section in the Methods stating when the research was conducted.

2) Need to justify in the text why just BMJ was used. Was it about access to editors' notes? This might be good reason (but makes the lack of years more bothersome).

Comment: We used the BMJ as one of the authors (SS) works for the journal and has access to all the backmatter associated with submissions. Not all journals allow researchers access to this data,

however the BMJ has a history of conducting journalology research. As it is a large general medical journal it publishes lots of trials in a year on a wide range of clinical topics. By using the BMJ we were able to demonstrate that the problem is not specific to a single discipline. We also used the BMJ as it is generally considered to be a leading journal and by demonstrating that interventions are poorly described in a leading journal it suggests that the situation is likely to be worse in other journals.

Change: We have added a new section in the Methods describing the setting.

3) If results are to be translated into practice, would there be research guidelines developed? Is the primary publication the best source of information to describe the treatment? If the treatment is to be used elsewhere, would researchers/practitioners not contact the original researchers? Would publication of protocol help?

More detailed guidelines and tools are clearly needed. Thus far CONSORT have 3 (overlapping) intervention extensions (non-pharmacological, herbal, and acupuncture – www.consort-statement.org/extensions/), but a generic checklist with supplementary lists is needed. Ideally the full description should be published with the primary article, but this often is not feasible, e.g. with extensive training materials. Supplements and additional materials should be available at the time of publication, since researchers may not respond, may retire or move, etc.

Change: We have spelled this out further in the final two paragraphs of the Discussion, including mention of the 3 current CONSORT extensions.

4) A CONSORT extension is referenced. Is this already in play and do people use this? Was it in 2006?

See above

5) The paper only talks about papers that were chosen for publication in BMJ. What of those that weren't? Were any rejected only because the description of treatments had been inadequate?

Comment: We did not look at rejected papers and focused only on published papers, because we wanted to examine what changed through the whole process from initial submission to final paper. However, it is unlikely that a paper would be rejected from the BMJ solely for this reason. Poor treatment descriptions are rectifiable so the editor would ask for clarifications from the author rather than reject a paper for this reason.

6) It is concerning that papers were seen as inadequate even when problems were highlighted to authors prior to publication

Comment: We agree! No change requested.

7) What is "no constraints" in Figure 2?

Comment: We already describe each element and the global item (no constraints) in the Methods section:

“Raters also completed an additional subjective global item to indicate whether the treatment was sufficiently described for them to replicate it if there were no resource or training constraints (no constraints).”

Change: We have also added a footnote to each figure stating that the full description is provided in Box 1.

8) Intro: is it fair to describe homeopathy as a treatment? Probably not.

Comment: CONSORT refers to homeopathic treatments so we feel it is a fair description:
Dean ME, Morag K, Coulter MK, et al. Reporting Data on Homeopathic Treatments (RedHot): A Supplement to CONSORT. *Forsch Komplementarmed* 2006;13:368-71.

9) Whose fault is missing data? Author, reviewer, editor? Seems that reviewers commonly asked for information that wasn't provided in the final paper.

Comment: We do not feel that it is appropriate to apportion blame for missing elements – we think all 3 need better guidance, tools, and to work together. Similar flaws of the peer review process are well documented in the literature.

10) Checklist seems to be compared to CONSORT. Is the development process similar? It seems that CONSORT is an internationally developed consensus of points, but the checklist is the work of but three people.

Comment: We are not comparing the checklist with CONSORT. We are merely demonstrating that there are inadequacies in the way interventions are reported using a simple checklist. The checklist is not validated but is offered as a useful starting point for editors and reviewers.

11) Where all points in the checklist relevant to all studies? If not, how was this accounted for in the % provided?

Comment: All the aspects included in the checklist are relevant to all studies. They are generic components that are important to the description of all interventions. Sometimes the answer was very simple, e.g, for a one-off procedure the “schedule” was “once”.

12) “For each checklist item the proportion of adequately described features ranged from 47% to 94%” I misunderstood at first that this was % of studies for a given checkpoint rather than the % of points for a given study. Perhaps this could be clearer?

Comment: We have revised the text to say “For each checklist item the proportion of trials with adequately described features ranged from 47% to 94% (Figure 1).”

13) Production quality of figures 1 and 2 is low.

Comment: We have revised the figure quality and uploaded as TIFF files.

Reviewer: Dr Steve George

We have checked the punctuation and corrected where appropriate.

VERSION 2 – REVIEW

REVIEWER	Matthew Sydes Senior Scientist MRC Clinical Trials Unit, London
REVIEW RETURNED	17-Oct-2012

THE STUDY	There are a couple of places that refer to Reference 10 being in Evidence Based Medicine but it is listed as being in BMJ in the reference list. Are there other similar problems with the other references? Perhaps other references got out of line?
RESULTS & CONCLUSIONS	I am still concerned by the fact that this review is from many years ago and that the authors cannot be sure these points have not already been addressed. I would encourage the authors to quickly produce an updated report of papers from 2011 in the same journal and to submit this for publication in the first half of next year. Better yet, perhaps such a project could be trailed in the conclusions?
GENERAL COMMENTS	<p>1. MODERATE :: Section :: Results :: Text ref :: “We identified 99 problems...” :: Comment :: I wonder how serious all of the problems were and whether it is right to group them all together. For example, I have been involved of trials of rather sophisticated radiotherapy that only a handful of sites were able to perform. I suspect that it would be obvious that you couldn't give this type of radiotherapy at any centre if you don't have the machine to give it. If the paper failed to mention the selected tertiary care centres, would this be a major problem? I suspect not. It would be an oversight of a potentially useful piece of information. I could imagine other instances where it would be important to give the location, for example, oral chemotherapy drugs with a high chance of anaphylaxis that need to be given at the hospital rather than at home (although after the first “cycle” at home might be fine...).</p> <p>2. MINOR :: Section :: Results :: Comment :: Is the paper the best place to find out how treatment was given in order to reproduce it? If a paper shows sufficiently positive data, are these not followed-up by public sharing of the protocol or publication of guidelines?</p> <p>3. MODERATE :: Section :: Discussion :: Comment :: The Discussion talks quite a bit about the inadequacies of peer review. I am feeling some sort of pressure here as if this peer reviewer was being tested!</p> <p>4. MODERATE :: Section :: Discussion :: Text ref :: Data sharing --- doi:10.5061/dryad.cljv0 :: Comment :: I cannot get this link to work. Should I be able to follow this? If so, can it be checked? If not, why list it?</p>

VERSION 2 – AUTHOR RESPONSE

Response to reviewer's comments

There are a couple of places that refer to Reference 10 being in Evidence Based Medicine but it is listed as being in BMJ in the reference list. Are there other similar problems with the other references? Perhaps other references got out of line?

The references have not gone out of line. Our previous analysis was based on papers that were published in the journal Evidence Based Medicine and we published the paper describing that work in the BMJ (reference 10).

We think this is clearly stated in the Methods section:

“our own analysis of poorly reported trials abstracted in the journal Evidence Based Medicine[10]”

And in the Discussion:

Our findings are consistent with our earlier analysis of 80 RCTs and systematic reviews published in the journal Evidence Based Medicine where approximately a half (51%) had an “inadequate” description of the treatment[10].

I am still concerned by the fact that this review is from many years ago and that the authors cannot be sure these points have not already been addressed. I would encourage the authors to quickly produce an updated report of papers from 2011 in the same journal and to submit this for publication in the first half of next year. Better yet, perhaps such a project could be trailed in the conclusions?

We agree that it is possible that the situation has changed and do suggest that further research is conducted on a more recent time point in the Discussion. We would hope to be able to do this research ourselves but would be more interested in testing an intervention to try to improve the reporting of descriptions eg perhaps we can encourage the BMJ editors and reviewers to use the checklist in practice and see if this results in an improvement in reporting.

PG is also currently in negotiation with the CONSORT group to develop a generic checklist, so anything further should wait until that is done.

1. MODERATE

:: Section :: Results

:: Text ref :: “We identified 99 problems...”

:: Comment :: I wonder how serious all of the problems were and whether it is right to group them all together. For example, I have been involved of trials of rather sophisticated radiotherapy that only a handful of sites were able to perform. I suspect that it would be obvious that you couldn't give this type of radiotherapy at any centre if you don't have the machine to give it. If the paper failed to mention the selected tertiary care centres, would this be a major problem? I suspect not. It would be an oversight of a potentially useful piece of information. I could imagine other instances where it would be important to give the location, for example, oral chemotherapy drugs with a high chance of anaphylaxis that need to be given at the hospital rather than at home (although after the first “cycle” at home might be fine...).

Comment: There were a total of 99 problems, but we also break these down to those associated with each checklist item. To categorise them by level of severity would be subjective.

Change: We have changed the text to indicate that the problems ranged in seriousness.

“We identified 99 problems, ranging in seriousness, with the descriptions of the interventions in the published versions.”

2. MINOR

:: Section :: Results

:: Comment :: Is the paper the best place to find out how treatment was given in order to reproduce it? If a paper shows sufficiently positive data, are these not followed-up by public sharing of the protocol or publication of guidelines?

Comment: Guidelines are usually weak in treatment descriptions and are constrained by the descriptions in the published studies, and protocols are still rarely shared publicly. In some cases the paper is the only place to find the information. Also, researchers and clinicians do not always seek out further information so it is important to publish accurate and complete descriptions in the first place. We have acknowledged that due to word limits this might not always be possible but suggest that this information is linked to or provided in a different source.

3. MODERATE

:: Section :: Discussion

:: Comment :: The Discussion talks quite a bit about the inadequacies of peer review. I am feeling some sort of pressure here as if this peer reviewer was being tested!

Comment: No change required.

4. MODERATE

:: Section :: Discussion

:: Text ref :: Data sharing --- doi:10.5061/dryad.cljv0

:: Comment :: I cannot get this link to work. Should I be able to follow this? If so, can it be checked? If not, why list it?

Comment: This is the link provided by Dryad. Perhaps it doesn't work until the paper is published?