BMJ - Decision on
Manuscript ID
BMJ.2018.045186

Body: 25-Jul-2018

Dear Dr. Crocker

Manuscript ID BMJ.2018.045186 entitled "Assessing the impact of patient and public involvement (PPI) on enrolment and retention in clinical trials: a systematic review and meta-analysis"

Thank you for sending us your paper. We sent it for external peer review and discussed it at our manuscript committee meeting. We recognise its potential importance and relevance to general medical readers, but I am afraid that we have not yet been able to reach a final decision on it because several important aspects of the work still need clarifying.

We hope very much that you will be willing and able to revise your paper as explained below in the report from the manuscript meeting, so that we will be in a better position to understand your study and decide whether the BMJ is the right journal for it. We are looking forward to reading the revised version and, we hope, reaching a decision.

Please remember that the author list and order were finalised upon initial submission, and reviewers and editors judged the paper in light of this information, particularly regarding any competing interests. If authors are later added to a paper this process is subverted. In that case, we reserve the right to rescind any previous decision or return the paper to the review process. Please also remember that we reserve the right to require formation of an authorship group when there are a large number of authors.

Thanks!

Daoxin Yin
dyin@bmj.com

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Report from The BMJ's manuscript committee meeting

These comments are an attempt to summarise the discussions at the manuscript meeting. They are not an exact transcript.

Members of the committee were: Wim Weber (chair), Richard Riley (statistician), Sophie Cook, Jose Merino, Elizabeth Lower, Georg Roggla, Daoxin Yin, Tiago Villanueva

Decision: Put points after the stats report

Detailed comments from the meeting:

The committee agreed that it is a very important topic. The 7th decision letter is from our statistician (Prof Richard Riley), please pay close attention and follow all the instructions. And editors particularly anticipate the replies to heterogeneity and

expect the authors can explain, interpret and discuss the PPI appropriately. Please also make the point-by-point replies to other reviewers' comments.

Comments from Reviewers

Reviewer: 1

Recommendation:

Comments:
I found this study very interesting and I felt it was very well written and explained, even for non-scientists. This was then "explained" by revealing that one of the authors is a patient partner. To me as a patient reviewer this made all the difference to reading and understanding the study. The other aspect I also found very positive and important was the distinction between PPI with no lived experience and PPI with lived experience. I have no comments to the authors, other than that I felt the findings etc were excellently explained.

Additional Questions:
Please enter your name: Kerstin Morrison

Job Title: Teacher

Institution: Primary school

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

Have you in the past five years been employed by an organisation that may in any way gain or lose financially from the publication of this paper?: No

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Reviewer: 2

Recommendation:

Comments:
A very well written piece of work. As a patient advocate I believe phenomenology "the lived experience" as research is not seen enough. A perspective at the grass

root level doesn't always match academic recommendations- in this respect I believe that the appropriate papers were sourced and reviewed, with the relevant studies included. The authors provide data for rationalizing their decision, and provides a digestive "layman's summary" of information. Research such as this can provide quality improvements strategies to healthcare.
The aim to measure I believe succeeded and explores various impact. There is a clear authorship disclosure and I believe a realistic analysis could divulge instruments and mechanisms to better support. The lack of patient lead, patient incorporated research is lacking- lived experience from patient perspective could be key in better supporting

Additional Questions:
Please enter your name: Julie Sprakel

Job Title: Founder & President

Institution: Think Pink: Bahrain Breast Cancer Society

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

Have you in the past five years been employed by an organisation that may in any way gain or lose financially from the publication of this paper?: No

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Reviewer: 3

Recommendation:

Comments:
First, this study is a well-designed and well-conducted systematic review. The results make a significant contribution to our understanding of the impact of PPI on enrolment in clinical trials. Therefore, the review deserves to be published.

Second, below please find my answers to the patient perspective questions.

Question 1: ARE THE STUDY'S AIMS AND THE ISSUE AND QUESTIONS THAT THE PAPER ADDRESSES RELEVANT AND IMPORTANT TO YOU AS A PATIENT? DO

YOU THINK IT WOULD BE RELEVANT TO OTHER PATIENTS LIKE YOU? WHAT ABOUT CARERS?

As a patient and a patient research partner I find patient and public involvement (PPI) in research very important. Equally important is the assessment of any impact such involvement may have.

From a researcher/funder/taxpayer point of view the main focus of such assessments would perhaps typically be on the effectiveness or cost-effectiveness of PPI, whereas for patient research partners the focus may be different. For patients who donate their time to take part in research the most important thing may well be that they feel that they are being treated as equal partners and that their viewpoints are being acknowledged and incorporated somehow. In short, that their participation is meaningful and worthwhile. I would like to see more qualitative studies exploring patient partners' experience and perception of their role as patient research partner.

I find that the aim of the present review – Assessing the impact of PPI on enrolment and retention in clinical trials – to be of more immediate interest to researchers and funders than to patients and patient research partners.

Question 2: ARE THERE ANY AREAS THAT YOU FIND RELEVANT AS A PATIENT OR CARER THAT ARE MISSING OR SHOULD BE HIGHLIGHTED?

The authors quote the patient partners involved in this study as arguing that "a trial that recruits more quickly will ultimately benefit patients more quickly". I think that if I had been involved in this study I would have seen it as part of my role to raise some of the following critical questions:

- Could there be any negative implications of patient involvement in enrolment and retention in clinical trials?
- Should we, as patients, naively assume that all trials are conducted for our benefit?
- Should we automatically endorse every trial?
- Do we possess the knowledge and skills to critically assess the risks involved on behalf of our fellow patients?
- Is it ethical for patients to help 'persuade', directly or indirectly, other patients to enrol in trials?

Question 3: FROM YOUR PERSPECTIVE AS A PATIENT, WOULD THE TREATMENT, INTERVENTION STUDIED, OR GUIDANCE GIVEN ACTUALLY WORK IN PRACTICE? IS IT FEASIBLE? WHAT CHALLENGES MIGHT PATIENTS FACE THAT SHOULD BE CONSIDERED?

NA

Question 4: ARE THE OUTCOMES THAT ARE BEING MEASURED IN THE STUDY OR DESCRIBED IN THE PAPER THE SAME AS THE OUTCOMES THAT ARE IMPORTANT TO YOU AS A PATIENT? ARE THERE OTHERS THAT SHOULD HAVE BEEN CONSIDERED?

Not quite, cf. the above comments.

Question 5: DO YOU HAVE ANY SUGGESTIONS THAT MIGHT HELP AUTHOR(S) STRENGTHEN THEIR PAPER TO MAKE IT MORE USEFUL FOR DOCTORS TO SHARE AND DISCUSS WITH PATIENTS?

The authors could incorporate, in a sentence or two, the dilemmas of patient involvement in enrolment in clinical trials mentioned above.

Question 6: THE LEVEL OF PATIENT INVOLVEMENT IN THE RESEARCH DESCRIBED, AND IF AND HOW IT COULD HAVE BEEN IMPROVED

The patient involvement in the present study is described in some detail as part of the Methods section. Apparently patients were involved at every stage of the research process, from planning the study to writing the article. However, only one patient partner took part in the entire process. It would how been nice to know the reasons for this. Also, instead of just stating that "PPI has been a wholly positive experience for us and there are no negative outcomes to report", it would have been good to report all three patient partners' experience as well.

Additional Questions:
Please enter your name: Mette Toft

Job Title: patient, patient research partner

Institution: none

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

Have you in the past five years been employed by an organisation that may in any way gain or lose financially from the publication of this paper?: No

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Reviewer: 4

Recommendation:

Comments:

Reviewer: Kristin Liabo, Senior Research Fellow, University of Exeter Medical School

This is an impressive piece of work to disentangle claims that working with patients and carers in research can help with participant recruitment. The study has sound methodology which draws on standard (but often ignored) systematic review methodology. Considering the current demands for patient and public involvement by most health research funders, the results are very important to researchers, research bureaucrats, and patients who want to work with researchers in a partnership capacity. The results are particularly interesting to anyone affiliated with Clinical Trials Units. Because of the broad evidence-base on which this study draws its conclusions the findings have international relevance. This study is a good contrast to many descriptive accounts of 'PPI'.

Overall, this reads well, although it might be less accessible to someone new to patient and public involvement. The article reflects some of the ambiguity (or lack of clarity) in the field (which for lack of an established name can be called 'patient and public involvement' community). My comments below are not on the soundness of methodology, but a suggestion for how you might shift the reporting to be clearer:

First, while I don't agree with you that working with patients as partners equates to an intervention, I am convinced by your article that this works well for the purposes of your systematic review. This works, for me at least, since you have anchored it in trials' need for improved recruitment. My suggestion is therefore that you stick more consistently to this starting point throughout your reporting.

For example, on page 6, you suggest that "the consequentialist argument for PPI in clinical trials … is likely to play an important role in the adoption of meaningful PPI as routine…" Here, you leave the question 'how can we improve recruiting trials?' and focus on improving the argument for PPI through establishing an evidence base. The difference is subtle, but I believe your message would be clearer if it is written with the focus of improving trials, rather than also including arguments for improving or strengthening the case for PPI. I know they link, but I don't think this is purely a semantic issue: the first message is clearer if you leave out the second.

In regards to your title, this message could be reinforced by changing it to something like "How can we improve recruitment rates in clinical trials? Would working with patients on the study planning help?" (I appreciate I am not particularly good at titles!)

If you, and the editors, agree with this point, you would need to change your introduction and anchor it in literature on trial recruitment. Unfortunately I am not familiar with the problems and solutions reported elsewhere to make any suggestions, but I believe this study could fit nicely there rather than as it currently does: in-between methods studies to improve trials and studies that seek to evidence the importance of PPI. This sharpening of your focus would also have implications for your recommendations for future research (p16) where you would anchor this in all other strategies for improving recruitment (as well as your current focus on understanding patient partnership work more).

Second, swapping the acronym PPI with full, descriptive, words might also improve clarity. For example, on page 11 you say that studies 'used PPI'. I believe this would read better if you said 'worked with' or 'involved patients in'. I sometimes find it difficult to understand what the PPI and the non-PPI interventions mean in the context of the sentence and spelling out words is likely to help with this. For example, also on page 11 you say that "Many of the PPI interventions also included non-PPI components… " I find this quite confusing because in my experience, when working with patients, it is often not easy to disentangle which suggestions for recruitment (or any other decision on study design) came from researchers and which came from patients. I appreciate this will add slightly to your word count. I believe it is important to get this right and delete some details or shorten sentences elsewhere.

Some details which as a typical peer-reviewer I can't help comment on (but which are less important than my two points above):

I would recommend cutting details on previous studies to assess impact from involvement (keeping these references but cutting it down) and details on your very comprehensive and impressive methods to make room for an example or two of what patient and carer involvement might look like. This would help people new to it to envisage what the intervention you are referring to looks like. The INVOLVE definition is helpful, but could be cut to make room for something more descriptive.
As mentioned before I was confused by the non-PPI reference (e.g. page 11 and 15).
On page 12 you refer to the study where involvement was associated with lower enrolment. You do not say what kind of involvement this was, but you do describe the involvement of the most successful trial (Vincent et al). It would be helpful to have the same information in the text on both trials, especially if the studies worked with people in similar ways.
I am unclear, on page 14, why you refer to not identifying any studies which assessed the impact of PPI in developing the trial question or designing the trial itself. Do you mean impact from this kind of involvement on recruitment?
Also on page 14 you say that it is unclear how PPI contributors can benefit research through their role as 'expert in lived experience' – do you mean in what formats they would be involved, or how they use their lived experience, or in regards to what roles? Perhaps all? I found this a bit vague, but might be because my head is in the particularities of involvement on a daily basis.
The last paragraph on page 14 is also a bit unclear. When you say "none of the PPI interventions included people with lived experience of the health condition under study… " do you mean the interventions in the studies that evaluated the impact on retention or do you mean all studies? Because the paragraph starts with the retention studies I wondered whether this second sentence related to the first, or if it was making a separate point?
Table 1: Intervention: is there some typos in the first sentence? Meaning is clear but the structure is odd. Do you mean "A trial methodology intervention which was consistent with the INVOLVE definition of public involvement"? Late in this same cell it sounds like you included it as PPI if researchers or health professionals had the condition under investigation? This sounds a bit odd to me, but perhaps this is common practice? It illustrates the whole variety of forms that 'PPI' can take but I wonder how people balance that those different hats.
I look forward to seeing the published version of this work.

Additional Questions:
Please enter your name: Kristin Liabo

Job Title: Senior Research Fellow

Institution: University of Exeter Medical School

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

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Reviewer: 5

Recommendation:

Comments:
This is a well conducted systematic review of the impact of PPI interventions on recruitment and retention in clinical trails. Although the review examined a wide range of variables, it was not possible to be specific about which aspects of PPI impacted on trial retention. While this is useful and thought provoking data I feel it adds little to what is known explicitly or implicitly on the subject. My recommendation would be that the authors incorporate the findings from their ongoing realist analysis with this review with and publish both together. I feel that this would give a more rounded and informative analysis as, in my opinion, details of the interventions are what readers will be looking for.

Additional Questions:
Please enter your name: Roberta James

Job Title: SIGN Programme Lead

Institution: Healthcare Improvement Scotland

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

Have you in the past five years been employed by an organisation that may in any way gain or lose financially from the publication of this paper?: No

Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper?: No

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Reviewer: 6

Recommendation:

Comments:
Thank you for the opportunity to review this interesting paper.

Patient and public involvement is rightly seen as a critical part of the delivery of health services research, but there is a developing debate about its impact, over and above any moral arguments about its importance

One of the oft-made arguments about the benefits of PPI is the potential to make studies more acceptable to patients (both in terms of their aims, and the specifics of how they are run), which may have impacts on recruitment and retention, but the evidence is fairly weak. If PPI was shown to demonstrably improve recruitment and retention through enhancing acceptability, this would be a very high profile finding, of great interest to the research community, and the paper likely highly cited.

This review attempts to explore whether PPI has those impacts through a systematic assessment of the available evidence, and is a welcome addition to the literature. The methods of the review are generally strong, with a good range of databases searched, and a decent number of studies included in the analysis. The process of the review is conventional and I could identify no major issues in terms of the mechanics of the review.

I had two concerns. The first related to the definition adopted, and the implications for the range of studies included. The second concerned the types of studies included, and the data analysed.

The introduction includes a very broad definition of PPI, but I am not sure that is sufficient for the review, and greater detail could usefully be provided on the range of interventions included in the study. Table 3 does provide some detail, but it is quite limited. My understanding is that their 'take' on the scope of PPI is quite broad. For example, the Du et al (2008) study is of a video intervention, and reading the detail does not suggest it is PPI as conventionally understood in the UK (although I can understand the logic of its inclusion). Likewise, Dear (2012) is a test of a 'consumer-friendly website', while Man (2015) is a trial of user testing (one in which I was involved, and which we did not conceptualise as PPI, although it is reasonable that others do).

Again, I think these inclusions are justified, but I am not sure my initial reading of their paper really made it clear the range of interventions being considered here. The highlight findings of this paper will be potentially very high profile, and it is really important that readers (especially readers of the abstract) are aware of what is being tested here. There is a slight danger that readers will make assumptions about 'PPI' in the title. The authors could be encouraged to highlight the fuzzy boundaries here a little more clearly, and highlight how their definition relates to conventional understanding of the term 'PPI'.

I think the extension of the study beyond trials is justified, but I was a little unclear as to what these studies looked like. For example, the example given is a study looking at the effect of PPI in the early stages of trial design. What did such a study look like, as it was not entirely clear what the comparator was in such a design? This might be usefully clarified with some examples, as this is clearly a slightly unconventional literature.

In the same way, more detail on the data extracted from the non-randomised studies would be useful. Again, I am interested in exactly what data were extracted from non-trials, and more details and examples might help here. For example, I was unsure how the data for Iliffe (2003) for the meta-analysis were derived from the paper, as it was not clear to me how they went from the figures in the paper to the quoted odds ratio. Initially I had the same issue for Wisdom (2002) as I was not clear where the 1177 sample was derived, although digging into the detail of the paper eventually made it clearer.

I think it would be really helpful to actually include the recruitment data analysed (i.e. numerator and denominator in each 'arm') in the Figure, rather than just the overall sample size. This would help people understand what was being analysed, and how it related to the data in each paper. It would also be useful to clarify whether all the comparisons were contemporaneous, or whether some related to rates being compared across different time periods of the trial.

The abstract suggests that the effects of PPI are not influenced by study quality, largely on the basis that the results are significant irrespective of the inclusion or exclusion of high risk of bias. However, the magnitude of the effect is quite different, and this might be made clearer. It also might be helpful to give an idea of what sort of effect that might be demonstrated in a conventional trial, making some reasonable assumptions about baseline response rates. The effect that they have demonstrated is important, but quite modest, and it is important that people are aware that this is just one way of making improvements to trial recruitment. Being more explicit about what those effects might look like for a trial would be useful

The authors might also be encouraged to be more specific as to the types of PPI that need further evaluation, which may relate to their comment on mechanisms.

I was not sure why the result around lived experience was 'unsurprising'? I felt that this paragraph was a little unclear and would benefit from rewriting.

Additional Questions:
Please enter your name: Peter Bower

Job Title: Professor of Health Services Research

Institution: University of Manchester

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

Have you in the past five years been employed by an organisation that may in any way gain or lose financially from the publication of this paper?: No

Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper?: No

If you have any competing interests <A HREF='http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/declaration-competing-interests'target='_new'> (please see BMJ policy) please declare them here: I was the PhD supervisor of one of the authors, and we have 1 current shared grant

One of my trials was included in the review

Reviewer: 7

Recommendation:

Comments:
This is a very interesting study. To me, it is an excellent example of a situation where there is expected to be heterogeneity (due to the broad range of interventions and disease areas), but still a summary of the evidence is important to gauge the average impact of PPI and, indeed, the range of PPI impact across different settings. I think the authors have done well to convey this, in particular by emphasising that their pooled results represent average affects, and by reporting prediction intervals to disseminate the range (heterogeneity) more clearly. It raises debate and discussion for new research. There are some strong limitations, but I think it adds an important starting point for further work. I have reviewed this from a statistical perspective, and do have some recommendations and comments for improvement:

1) The inclusion of non-randomised studies was confusing to me. Indeed, the findings only seem to be strong when excluding these studies in the end. As there is already potential heterogeneity across different types of PPI in the trials setting alone, I find the extra heterogeneity from mixing trials and observational studies to be hard to justify, at least at the main analysis. I would prefer, therefore, that the main (primary) analyses are those restricted to just the trial evidence.

2) "We did not find evidence that PPI interventions improve retention in clinical trials (OR 1.20; 95% CI 0.68 – 2.12)." – needs to be re-worded as clearly confidence interval is wide; indeed, there is also no clear evidence that PPI interventions do not improve retention in trials. Same comments applies to: "Pooling the data in a meta-analysis found that, on average, PPI interventions were not significantly associated with retention of study participants". I'm sure the authors agree that lack of statistical significance is not evidence of no effect, and actually here may merely reflect low power. We cannot rule out potentially large effects (in either direction). So suggest a more balanced interpretation.

3) "This finding remained after excluding studies at high risk of bias (including all non-randomised studies) (OR 1.17; 95% CI 1.04 – 1.32; 95% prediction interval 1.01 - 1.36)." – there is a big drop in the OR when only considering the high quality evidence; another reason for my suggestion to focus on the trials only evidence as the main analysis. It is reassuring to see that the prediction interval for the OR in a new trial setting contains values > 1, and so – even when accounting for the uncertainty and heterogeneity – it appears likely that PPI involvement is effective. But is the effect large? That is, can the authors translate to real terms what an OR of 1.17 would actually mean?

4) Prediction intervals are calculated how? In a frequentisits setting they are only approximate; in some situations they do not perform well in terms of coverage. It is worth emphasising this.1

5) Egger's test in inappropriate for odds ratios. Better to use Peters' test, for example.2 3

6) "Heterogeneity was quantified using the I-squared statistic" – the I2 statistic does not quantify heterogeneity directly; indeed it is a misleading measure in that regard.4 Better measures are the estimate of heterogeneity (or indeed the prediction interval).

7) Confidence intervals from the meta-analysis should be re-calculated to acknowledge the uncertainty in the heterogeneity estimates, for example using the Hartung-Knapp method.5 6

8) What type of PPI intervention is best? Can't say. What is the magnitude of enrolment improvement expected when using PPI? This relates to end of my point 3 – the findings are clearly limited, which is fine, but this needs to be outlined more clearly in the abstract and what this study adds. Recommendations for further research should be about identifying what type of PPI intervention is best for particular settings and contexts.

9) funnel plot assessments are better referred to as examination of smalls study effects, rather than publication bias (the latter is just one possible cause)

10) In the what this study adds, it would also help to emphasise that the type of PPI strategy varies considerably across studies

11) All meta-regression and subgroup analyses should be reported with caution due to potential for study-level confounding.

12) "Many of the PPI interventions also included non-PPI components, such as the involvement of other stakeholders or experts" – so how can we distinguish between the effect of PPI and the effect of experts? Which is the one leading to improvement? Would this lead to a higher risk of bias assessment? Why not start by restricting to those that actually had a pure PPI component to the intervention? Should this also be added to the limitations in the abstract and what this study adds?

13) Six studies could not be included due to insufficient data. Did the authors try to indirectly obtain this data from other information, or even contact the original authors?

14) "…produced a 95% prediction interval of 1.01 to 1.36, suggesting that any new, high quality randomised study of a PPI intervention would almost certainly demonstrate a positive impact of PPI on enrolment." – careful with this

interpretation. The prediction is for a PPI strategy and setting as observed within the included trials, and thus cannot be generalised beyond this as inferred by the authors' statement. Indeed, more is needed about the exact PPI interventions used in the trials that leads to this prediction interval. Did they include non PPI components for example? I think, as per earlier comment, having a section dedicated solely to the trials would aid the clarity and translation of this piece of work, before then broadening out to observational studies also.

15) "PPI in developing patient information sheets was not significantly associated with retention,(36, 39) while using lay Community Health Advisers to support participants (the only PPI intervention specifically targeting retention) led to a significant improvement in retention rates (OR 2.52 [95% CI 1.82 – 3.50])."
- but was there strong evidence of a difference between these subgroups based on meta-regression?

16) Are there small study effects in the trial-only analysis? It does not appear so. This is important to clarify.

I sincerely hope this review helps the authors and the BMJ going forward.

Best wishes, Richard Riley

Reference List

1. Partlett C, Riley RD. Random effects meta-analysis: Coverage performance of 95% confidence and prediction intervals following REML estimation. Stat Med 2016.
2. Sterne JAC, Sutton AJ, Ioannidis JPA, et al. Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. BMJ 2011;342:d4002.
3. Peters JL, Sutton AJ, Jones DR, et al. Comparison of two methods to detect publication bias in meta-analysis. Jama 2006;295(6):676-80.
4. Rucker G, Schwarzer G, Carpenter JR, et al. Undue reliance on I(2) in assessing heterogeneity may mislead. BMC Med Res Methodol 2008;8:79.
5. Cornell JE, Mulrow CD, Localio R, et al. Random-effects meta-analysis of inconsistent effects: a time for change. Ann Intern Med 2014;160(4):267-70.
6. Hartung J, Knapp G. A refined method for the meta-analysis of controlled clinical trials with binary outcome. Stat Med 2001;20(24):3875-89.

Additional Questions:
Please enter your name: Richard Riley

Job Title: Professor of Biostatistics

Institution: Keele University

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

Have you in the past five years been employed by an organisation that may in any way gain or lose financially from the publication of this paper?: No

Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper?: No

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