Author’s response to reviews

Title: Description of complex interventions: analysis of changes in reporting in randomised trials since 2002

Authors:

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Author’s response to reviews:

Reviewer #1: The authors set out to assess whether descriptions of multicomponent non-pharmacological interventions evaluated in randomised trials are improving. They looked trials in two time periods around the publication of the CONSORT NPT statement.

The research questions are important and the methods used to answer those questions are appropriate. The conclusions are supported by the data and methods. I have some minor comments

1). Can the authors explain more why they feel things are improving?

Authors response:

We have now added the following new section in the discussion section:

Why have we found no improvement?

Trials continue to under report intervention descriptions. The reasons for this are multiple. There remains a likely lack of awareness of the need for adequate reporting. Journals still do not endorse the use of reporting guidelines, however even if they do it is likely that these policies are not always closely adhered to. Authors may have little steer from journals on what to include in regards to intervention description, even from those that endorse the CONSORT guidelines. The items on intervention description in the CONSORT extension statement for non-pharmacological treatments are broad. For instance, important details, such as the length and intensity of the intervention, are not specified (see Box one). Whilst the more recent TIDieR guideline provides more direction it was only endorsed in one journal in this cohort. Another reason for under-
reporting is that for some authors either novice or even experienced, they may feel overwhelmed with the growing number of reporting tools and they may not know which to select [13]. Furthermore, authors may be challenged because of the complexity of the intervention and their own lack of clarity on the key details (or active ingredients that are essential) to report. They may for example fear over-simplifying in providing a summary of the intervention’s content and delivery. Should this arise there is in general the opportunity to publish or make available the intervention on request in the format as a protocol, manual or separate paper describing the intervention in detail. However, this does not seem to be happening. In the more recent cohort in our study at best just over half (56%) of the authors documented a link to further intervention details.

2). Any different between CONSORT endorsers and non-endorsers?

Author response:

We found no difference between trials published in journals that currently endorse CONSORT to those that don’t. We present our new analysis of this in the results section. We discuss this in the discussion section, pointing out that there are limitations to this analysis since the journal may not have endorsed the CONSORT when the trial author submitted their paper.

3). Is there any correlation with impact factor?

Author response:

We found no correlation with the impact factor. We present our new analysis of this in the results section.

4). Why are protocols still not being published?

Author response:

In the discussion section, we have added the following:

Protocols are still not being published. Reasons may include authors’ lack of awareness of the opportunity to publish a protocol. Other authors may not appreciate the value of devoting additional limited time to this endeavour. Not all peer reviewed journals may accept protocols. Some authors may not want to publish a protocol, in case the intervention evaluated deviates in testing from what was originally set out in the protocol. For example, during the trial, if certain content may be found to be inappropriate in some way. Whilst changes to intervention content are acceptable and should be documented some authors may be unaware of this. Others may be aware, but have limited time to devote to justifying this in trial publications.
5). A fuller discussion around what journals and the wider scholarly community can do would be useful. It is now a decade since CONSORT NPT was published, so just raising awareness is not enough. Clear action is needed. For example, one suggestion is to weave reporting guidelines into the electronic submission process for a journal. This has been looked at by our group and results were positive although we are still not quite 100%, you may wish to discuss these:

http://www.sciencedirect.com/science/article/pii/S1743919117306301


Author response:

In the discussion section, we have revised and expanded our discussion on this topic:

Awareness raising of the need for reporting adequately interventions should be undertaken early, through education and training starting at university and continuing through professional education and continuous professional development. Moreover, academic institutions could have reporting polices or recommendations for staff undertaking research. Checking that a manuscript adheres to reporting guidelines should not be the last thing an author may undertake prior to submission for peer review consideration for publication. Documentation of key aspects should be embedded throughout the intervention and trial development and its analysis. In the case of developing complex interventions, greater attention should be paid early by research teams and research funders to the MRC and other intervention development guidelines. The inclusion of a statistician or other methodologist in a trial team has been demonstrated to improve quality of trial reporting [23].

Publishing groups and journal editors need to endorse reporting guidelines and provide links to initiatives like the EQUATOR guidance that help researchers to formulate research design that is robust and easy to report. Further evaluations need to explore why journals do not recommend CONSORT or other recommendation reporting guidelines, including the more extensive TIDieR statements. In those that do recommend guidelines it would be useful to explore how well they ensure authors adhere to them. In a recent survey, it was found that only 6 of the 59 leading pathology journals endorse reporting guidelines in their instructions to authors, and only one of these six required authors to submit a guideline reporting checklist [24]. Journals that implement a policy mandating the submission of a completed reporting guideline checklist for studies have been found to increase compliance and improve the quality of reporting [25].

Reviewer #2: The study investigates the evolution over time of reporting quality of complex interventions and adds considerable insights to the existing literature on the subject. The distinctiveness of the work is that two different periods of five years separated by the publication of the CONSORT reporting guidelines have been chosen in a comparative way. Overall, there was no evidence of improvement of the reporting complex interventions.
The authors wrote the article in a way that demonstrates good knowledge of the international reporting guidelines and their related issues. I make some comments here to prompt revision.

Background

Comment:

Page 3, lines 46-52: The authors stated that adequate description of healthcare intervention is required to foster applicability and generalisability. At least one reference of both aspects should be cited to sustain the author statement.

Author response: References added

Comment:

Page 4, Lines 1-7: To facilitate the lay audience understanding, it may be better to use the same wording for the terms « non pharmacological interventions » and « non-drug intervention ».

Author response: We now use the same term to describe the interventions of interest.

Comment:

Page 4, Lines 14-17: « However testing of complex interventions […] is needed with clear descriptions of the content of both intervention and control procedures ». I completely agree with this. However, the authors should include an explanation or a reference related to this absolute truth based on previous works on the subject.

Author response:

Reference added

Methods

Comments:

Page 8, line 43 (data analysis): The authors should specify the software used to carry out descriptive statistics.

Author response: We now state the software used.

Results
Comments:

Even if the study is ancillary to a Cochrane systematic review, the authors have to report a flow diagram of selected trial reports. In fact, as a methodological review, the figure will provide a global view of all applied inclusion criteria and restrictions considered in the method section (page 6).

Author response: A flow chart has been added

Comment:

Page 9, lines 5-7: the percentages of the « description of the comparator » reported in the text (40% Vs 34% for both times 1 and 2 respectively) seems to be different than those reported in table 1 for the comparator item (60% Vs 66% for both times periods respectively).

Author response:

We have now corrected these so both items.

Comment:

Page 9, lines 14-19: in the comparison of both time periods, it may be important to outline the significance of the percentage difference with a test.

Author response:

We did not want to statistically test the difference between times points for all 24 items due to the issues of multiplicity. We decided apriori to only statistically compare the quality score between time points. Consequently, we have not performed any additional tests comparing time points.

Comment:

Page 9, lines 26-33: as the authors used an overall quality score of 8 items to compare both time periods, how the related means were calculated should by specified in the data analysis section.

Author response:

This has been clarified in the text.

Comment:

Page 9, lines 38-43: whether trials that were published in a journal follow a CONSORT guidelines may be a factor of a better reporting quality of the intervention (appendix). Please consider reporting this information in the result section with a post-hoc chi-squared test. This should also be outlined in the data analysis section of the manuscript.
Author response:

We found no difference between trials published in journals that currently endorse CONSORT to those that don’t. We present our new analysis of this in the results section. We discuss this in the discussion section, pointing out that there are limitations to this analysis since the journal may not have endorsed the CONSORT when the trial author submitted their paper.

Discussion

Comment:

Page 9-10, lines 59-1: The authors have to use the same language to avoid spin. Indeed, as they reported to have found no evidence that reporting of complex interventions is improving, this should be written similarly in the discussion section.

Author response:

Thank you for highlighting that we have varied the way we have expressed our key finding. We now state throughout the manuscript we found no evidence of improvement of reporting.

Comment:

Page 9, lines 1-5: If the authors are mistaken in their reporting of percentages of the « nature of the comparator intervention or control » between the result section of the manuscript and the table 1, the impact of this sentence is not the same. This should be revised accordingly, with a focus on the right defective items (e.g. fidelity assessment as reported in the abstract).

Author response:

We now report fidelity. We also provide an example of another we believe needs highlighting.

Comment:

Page 10, lines 7-12: As mentioned in a comment above (see Results please), the impact of the CONSORT guidelines on the reporting quality of the interventions could be tested using a Chi2 test. If so, the authors have to revise this part of their discussion.

Author response:

We have as advised revised our discussion section.

Comments:

Page 11, line 14: It would be better to delete or replace the term « Fourthly ». There are no other ordinal adverbs before indeed. Page 11, line 33: please, delete the word « are ».
Author response:

Thank you we have changed these.

Comment :

Page 11, lines 35-40 : Please consider the previous comment about the way to quantify the potential impact of CONSORT reporting guidelines on quality of reporting. The choice of not restricting by journal may not be a limitation consequently.

Author response:

We have as advised revised our discussion section.

Comment :

Page 12, lines 17-29 : The authors extended their discussion on the issue of under-reporting of different trial aspects in general. Although many studies did not use TIDieR tool to assess the reporting quality of (complex) interventions, there are previous significant reviews in the literature that assessed the reporting quality of both interventions and methodological criteria (over time) in trials. Therefore, the authors should refer certain of these studies for both pharmacological and non-pharmacological interventions in a comparative way.

Author response:

We have added to the discussion section the following;

There are previous reviews that have assessed changes in the quality of reporting of trials [e.g. 14-18]. In those concerning reporting of the trial methods, improvements have been found [14-16]. For example, one study evaluated reporting over three decades of 20920 RCTs and found improvement in reporting of six methodological items, in particular in randomization sequence and allocation concealment [14]. In two of these studies any relationship to whether the journal endorsed CONSORT statements was explored. However, these studies did not assess reporting of intervention features. Others that have assessed reporting of intervention description have not found improvement [17,18]. For example, a Cochrane review exploring the impact of CONSORT statements on trial reporting, in its last version (published in 2012) found no difference in reporting of intervention between trials published in journals that endorse CONSORT and those that don’t [17]. Yu et al explored in two cohorts (trials published in 2003 and 2013) the reporting of items in CONSORT including CONSORT extension for Trials Assessing Non-Pharmacological Treatments. [18] Whilst they found overall improvements in reporting in 2013 compared to 2003 they did not in items relating to the intervention. Another study reported similar findings when comparing intervention reporting of cardiac rehabilitation over several decades (1975 to 2014) [19]. In sum, these studies show that while there has been improvement in reporting of methodological items in CONSORT this has not extended to intervention descriptions.
Comment :

Page 13, line 7 : It would be better to provide a brief conclusion section further in the text for a best clarity. If this is the case, the present paragraph may be entitled « implications and perspectives » with a reorganisation of the related arguments.

Author response:

We now provide a brief conclusion section at the end of the paper.

Comment :

Page 13, line 14-17: Since all the items (including the global score) were not only based on the CONSORT guidance (greater consideration of TIDieR in the extracted items), this statement may be wrong. Indeed, the mean's comparison is not suitable to accurately test the impact of the sole CONSORT guidance in this case.

Author response:

We have now removed the statement.

Bibliographic references

Comment :

Page 14, line 52 : For section consistency, the reference number 8 should be reported in the same style than the other.

Author response: We have corrected this.