Title: Active ingredients are reported more often for pharmacologic than non-pharmacologic interventions: an illustrative review of reporting practices in titles and abstracts

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Version: 5 Date: 8 February 2013

Author's response to reviews: see over
Dear Editor of Trials

Please find attached a revised manuscript entitled ‘Active ingredients are reported more often for pharmacologic than non-pharmacologic interventions: an illustrative review of reporting practices in titles and abstracts’. We would like to thank the reviewer for taking the time to read our article and for their very useful comments. We have carefully considered and addressed all of these comments. Below, we have reproduced each comment. This is followed by our response, which is followed by the revision made to the manuscript. We hope you find this format useful.

Since we have added more detail specifically to the introduction and discussion sections, this has increased our word count considerably: we have attempted to reduce the word count in other sections of the paper and hope that you find this sufficient. We look forward to your response in due course.

Yours faithfully,

Nicola McCleary

For the author group
Reviewer Comments

Major Compulsory Revisions

1) Given the focus on active ingredients, the authors could elaborate a little more on the definition they provide in the introduction of the paper. A few more illustrative examples would be helpful in addition to the two terms in table 2 and box 3, especially for NPIs. For NPIs and BCIs I am still unclear whether the authors refer to intervention techniques (e.g. behaviour change techniques for BCIs) alone, or would also include the theoretical mechanisms through which an intervention is hypothesised to exert its effects?

Thank you for this useful suggestion. Details of the active ingredients for each included study (where specified) are now included in the summary table in additional file 4 (was additional file 3). The definition of ‘active ingredients’ has now been elaborated in the introduction, and a further illustrative example for non-pharmacologic interventions has been added to this explanation:

“The term ‘active ingredient’ is frequently used to refer to the element within a pharmacologic intervention (PI) which is responsible for its therapeutic action. In contrast with PIs, non-pharmacologic interventions (NPIs) are usually complex, containing several interacting components which are all necessary for the intervention to be effective (Box 1) [4]. The term ‘active ingredient’ was adopted in the UK complex intervention literature because early guidelines for the evaluation of complex interventions were based on the phases used to evaluate PIs [5].

The term ‘active ingredient’ refers to the components within an intervention that can be specifically linked to its effect on outcomes such that, if they were omitted, the intervention would be ineffective. For example, a cardiac rehabilitation intervention aimed at improving health-related behaviour associated with heart disease may focus on supporting smoking cessation, regular physical activity, and a healthy diet [6]. Specific techniques used may include goal setting, providing information on consequences of behaviour, and prompting self-monitoring of behaviour [7]. Provided these techniques have the potential to influence the health-related behaviour associated with heart disease (i.e. causally influence outcomes)[6], they can be described as active ingredients. Therefore, throughout this article, the term ‘active ingredients’ is used to refer to these components in both PIs and NPIs.” p. 4-5

We have also specifically stated in the introduction that we view active ingredients as distinct from the mechanisms through which an intervention has its effects:
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“It is important to note that this is distinct from the mechanisms of action of interventions (the underlying reasons why the active ingredients have their particular effects) [6].” p. 5

2) The manuscript might benefit from a stronger argument which supports the current review practice. Although title and abstract reporting practice is interesting in its own right (e.g. for systematic review purposes as the authors outline), the main question is whether this is also indicative of poor reporting within the full publication. Studies are seldom evaluated or replicated based on title or abstract alone.

In the introduction, we have strengthened our rationale for reviewing only titles and abstracts by explaining why accurate and comprehensive reporting in titles and abstracts is important:

“Accurate and comprehensive reporting of these components in titles and abstracts is essential [1, 8]. Abstracts are more widely circulated than full-text articles [9] and are generally the most widely available parts of articles [10]; Consequently, their content can have a greater than anticipated impact [8]. Inadequate specification of key components in titles and abstracts can have serious implications for systematic reviews, which are considered the best sources of evidence about the effectiveness of interventions [11]. Since reviewers base their initial inclusion decisions on abstracts [8], inadequate specification may result in studies being inappropriately rejected from the review, thus compromising review validity. Additionally, many readers use abstract content to determine whether full text retrieval is worthwhile [1, 10, 12], while in certain countries, many health care professionals have easy access to abstracts but not to full texts [1, 8]. For these reasons, it is important to investigate the quality of reporting in RCT abstracts.” p. 5

Uncertainty regarding the link between abstract and full text reporting quality is now addressed in the study limitations section:

“One final important limitation concerns the link between abstract and full-text reporting. Reviews of full text articles [17, 18] and reviews of abstracts [8, 9, 12, 35] have highlighted deficiencies in reporting. However, research is required to verify whether the quality of abstract reporting is linked to that of full text reporting. It is therefore not clear whether findings similar to ours would be obtained if full text articles were reviewed in the same way: this is an important follow-up evaluation.” p. 17

In addition, we have further supported our procedures by highlighting in the study strengths section that our review differs from other reviews of abstract reporting quality because we have specifically focussed on and compared the level of detail provided regarding different types of interventions:
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“The study of abstract quality is a fairly recent development [8], with most reviews focussed on reporting of trial components [8, 9, 12]. Many studies use the CONSORT abstract reporting guidelines to evaluate quality. CONSORT specifies that intervention details should be reported, but gives no guidance on how they should be reported: this is the first review of abstracts to focus specifically on the level of detail provided regarding different types of interventions.” p. 17-18

3) The authors mention in several sections of the manuscript that NPIs are typically more complex in terms of number components including ‘active ingredients’. Given these (and many other) difference of these two types of interventions the authors might want to elaborate on how informative can such a comparison to strengthen the study rationale.

Great point, thanks. In the introduction, we have added a stronger justification for comparing pharmacologic and non-pharmacologic intervention reporting standards by explaining the usefulness of this approach:

“Given the importance of accurate intervention reporting in titles and abstracts, an explicit comparison of reporting practices for PIs and NPIs would be useful for a number of reasons. Firstly, to establish whether there are similar disparities in the quality of abstract reporting between PIs and NPIs as there are for full-text articles. Reviews of full-text articles have illustrated how reporting of NPIs can be improved based on PI reporting practices; a comparative review of abstracts could similarly illustrate how the reporting of abstracts describing NPIs could be improved.” p. 7

We have also addressed this issue in the study limitations section:

“The many differences between PIs and NPIs may make comparison difficult to interpret: however, existing abstract reporting guidelines were designed to apply to both intervention types, implying that both abstract types should be written to a similar standard. We have shown this is not the case in these journals.” p. 17

Minor Essential Revisions

4) “Papers which were not the primary report of the study (for example secondary analyses of trial data) were excluded, as a full description of the intervention may legitimately not be provided in the title or abstract.” (p.7) – this argument might need revision as a full description will not be provided in the title or abstract for primary reports either.
Although it is often not possible to include a fully detailed description of an intervention in an abstract, one of the objectives of a primary research article should be to include a description of the intervention which focusses on the active ingredients and includes as much detail as is possible. Indeed, CONSORT guidance does recommend that abstracts include as full a description as is possible within the space limitations of an abstract. This may not be an objective of secondary research articles, where intervention details have presumably already been published. This justification for excluding abstracts reporting secondary trial data analyses has been added to the methods section:

“Papers which were not the primary report of the study (for example secondary analyses of trial data) were excluded. CONSORT recommends that although space limitations restrict abstract content, interventions should be described with enough detail to be fully understood [1]. This should be the objective of primary research reports. Intervention description is not necessarily the main focus of secondary research reports, and so a full description of the intervention may legitimately not be provided in the title or abstract.” p. 8-9

5) Please provide details for random paper selection of the 210 studies to allow replication (p.8).

Details of the sampling strategy to allow for replication were originally provided in additional file 1, which allowed for replication. These details are now included in a separate additional file (file 2) and have been made clearer. Further details of the sampling strategy have also been added to the methods section:

“To ensure the sample was representative of the population of studies considered, papers were sampled proportionally to reflect the proportions of PI and NPI reports typically published by these journals, rather than sampling an equal number of papers from each journal. The calculations performed to determine the numbers of PI and NPI reports to be sampled from each journal are included in Additional File 2.” p. 9

6) How were the different NPI categories created and defined? (p.9)

Non-pharmacologic interventions were classed as either behaviour change interventions; surgical interventions; devices; screening interventions; food supplementation; or rehabilitation interventions. These categories were created by reviewing the studies used in the piloting phase. These details have been added to the results section:
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“The interventions described within the 96 NPI reports were categorised as either behaviour change (when aimed at changing behaviour; 41 reports); surgery (10 reports); device (9 reports); screening (5 reports); food supplementation (involving a preparation aimed at supplementing diet; 5 reports); or rehabilitation (when aimed at restoring health/functioning; 5 reports). These categories were created based on the studies used in the piloting phase.” p. 11

Interventions which did not fall into any of these categories were not categorised. To allow readers to review the types of interventions evaluated, the intervention categorisations for each study have been added to additional file 4 (was additional file 3). This has been explained in the results section:

“An intervention type could not be specified for five papers (these were excluded from all subgroup analyses as it was unclear whether or not they were BCIs). The remaining 16 papers reported evaluations of interventions which could not be classified into any of the 6 categories mentioned previously (see Additional File 4).” p. 11

7) Is there overlap between the NPI categories (e.g. rehabilitation interventions might also be behaviour change interventions) or are these categories discrete? (p.9)

The description of the non-pharmacologic intervention categories added to the results section (included under comment 6) makes it clear that categories were discrete.

8) “The remaining 16 papers reported evaluations of various types of interventions (see Additional File 3).” – Additional file 3 does not contain any information of intervention categorisation (only details on publication, patient group and intervention target, sample size and number of sites). Categorisation information would be a useful addition to this information. Given the focus of this manuscript, it might be useful to include active ingredients within this table- this would also go towards addressing my above concern (comment 1).

Great suggestion. Details of the active ingredients for each included study (where specified) and intervention categorisations for each included study are now included in the summary table in additional file 4 (was additional file 3).

9) Given the ‘dropout’ of some of the studies, why did the authors not include further studies to arrive at a final sample 100 studies each for both overall categories, rather than having unbalanced numbers which makes comparison slightly more difficult?

Good point, this is something that we had not considered. The issue of study dropout and the fact that further studies were not sampled to arrive at a final sample of 100 studies each for both overall
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categories (which would have made comparisons easier) is now addressed in the study limitations section:

“Study dropout must also be highlighted; one duplicate, one non-primary RCT report and four reports describing both intervention types were removed from analyses. This resulted in unbalanced numbers of papers in the PI and NPI categories; these excluded papers could have been replaced such that an equal number of papers in each group were analysed.” p. 17

10) All data reported in this manuscript have been extracted and categorised by one researcher only. The authors might want to mention this in the limitation section of the manuscript.

This issue is now addressed in the study limitations section in the discussion:

“Data extraction, categorisation and analysis were carried out by one reviewer. However, any issues were resolved by discussion with the whole author team and there was general consensus regarding the data extracted during piloting.” p. 16-17

Additionally, more specific details of the study piloting phase have been added to the methods section to show that there was agreement with regards to data extraction at this point:

“The form was piloted by one researcher (NM) and a colleague (a trainee health psychologist). Data extracted in relation to components reported were converted into frequency data, and inter-coder agreement was assessed for each of the 10 pilot papers using the Kappa statistic. Kappa values ranged between 0.44-0.76, indicating moderate or substantial agreement for all 10 papers [26]. Minor changes were made to the form following piloting. Piloting indicated that the classification scheme could be used to extract relevant data from titles and abstracts and that the scheme was fully comprehensive in terms of the components of interventions typically reported in titles and abstracts.” p. 10

11) Minor point: Please remove track changes from additional file 3.

All previous tracked changes have been removed from additional file 4 (was additional file 3)

12) “We discovered that while ABM limits abstracts to 150 words [18]” – does this discovery mean that journals were not checked for abstract length before selecting them? This should be mentioned in the limitations section.

Journals were not checked for abstract word limits prior to the review. This was because, as specified in the manuscript, our criterion for selection was high journal quality, in order that we
investigated reporting practices of some of the highest quality journals. This issue is now addressed in the study limitations section in the discussion:

“Journal recommendations for abstract word length were not verified at the outset of the study, and so there was imbalance between the journals targeted. Abstract limits were not checked because, as specified previously, our criterion for journal selection was high journal quality. Interestingly, a lower proportion of BCI reports published in ABM reported the active ingredients in the title than those published in the other journals (17% vs. 31% studies, respectively), while a higher proportion reported the active ingredients in the abstract (60% vs. 67%, respectively). Thus, inclusion of journals with a range of word limit policies was informative.” p. 16

13) “a sensitivity analysis by removing the six papers published in ABM” (p.10). Does this mean that only 6 studies from ABM were included in the final sample (as additional file 3 would also suggest)? Why only so few, given that the journal was selected to contribute NPIs and BCIs specifically. This appears somewhat unbalanced given that random selection was employed. Is this by chance?

The reason that so few papers were sampled from Annals of Behavioural Medicine is due to the proportional sampling strategy used. This issue is now addressed in the study limitations section:

“Due to the proportional sampling strategy used, only six articles published in ABM were included. The sample reflected the relative frequency of publication: fewer RCTs are published in ABM than the other journals, therefore fewer were retrieved and sampled. Although this reflects the relative frequency of publication, this is a limitation given that this journal was specifically selected for inclusion of high-quality reports of BCIs.” p. 17

To further clarify of the sampling strategy used, details of the strategy (which were originally provided at the end of additional file 1) are now included in a separate additional file (file 2). Further details have also been added to the methods section, as specified above under comment 5.

14) Overall, I find Table 2 difficult to read and containing some redundant information. I suggest to omit any columns with the number of studies not including a component as this information is not necessary. In addition, the authors can either report % of studies coded as ‘yes’, or state the number coded as yes reporting out of how many in the header of the table, or a note at the bottom. This would make a comparison between the two types of studies much easier. Please also indicate significant differences in the table. The authors might also want to think about putting
table 2 in graphical form which would allow much faster processing of the information and would allow easy display of significant differences.

This is a great suggestion, thanks. Table 2 has now been removed, and figures 2 and 3 have been included in its place, incorporating the recommended edits to the data displayed.

15) Also, why does Table 2 provide examples for some components and not for others, and are examples taken from PIs, NPIs or a mixture?

Since table 2 has now been replaced with two figures, these examples are no longer included. However, details of the active ingredients for each included study (where specified) are now included in the summary table in additional file 4 (was additional file 3). In the introduction, the reader is now directed to table 1 for examples of other components.

16) In principle I think the boxes are a good idea to illustrate some of the points the authors make throughout the manuscript. However, the current use of boxes can be improved. These are not easily understandable and frequently change in layout and often contain little information.

Good point. All boxes have been edited to appear in the same format. Box 2 has been removed and the information added into the text:

“The active ingredients of a PI can usually be specified clearly in one phrase within a sentence (e.g., “Zoledronic acid” [15]). However, an NPI often cannot be specified so succinctly: as a result, intervention objectives are often specified, while active ingredients are often not reported (e.g, “self-management programme. The programme teaches patients medical, social and emotional self-management skills.” [16]). ” p. 6

In addition, Box 5 has been removed as this information is already included in the text.

17) In addition, the example in box 4 does not underline the point that the authors want to make (same term in the title linked to different descriptions in abstract). The second abstract describes the content of motivational interviewing and merely mentions CBT without further elaboration. Thus, in the second abstract CBT content is not described beyond the mentioning of the label (at least in the provided excerpt). A more illustrative example might be beneficial.

Thanks for this suggestion. A new example has been added to box 3 (was box 4) which more appropriately supports the point made in relation to reporting practices.

18) The authors mention one limitation, but need to expand this section elaborating on, e.g.: generalisability of findings, single researcher abstracting and coding data, word limit imbalance
between target journals, uncertain link between title/abstract reporting and overall study reporting, limited comparability between PIs and NPIs.

All of these issues are now addressed in the study limitations section. All but the issue of generalisability have been included above (see comments 2, 3, 10, and 12):

“Our findings may be generalisable to other general medical journals of similar quality; however the generalisability of our findings to other types of journals or conference abstracts may be limited.” p. 16

19) Do the authors deliberately refrain from providing a recommendation for active ingredient reporting practices for titles/abstracts (in addition to recommending standard labels)?

Further explicit recommendations for active ingredient reporting in titles and abstracts have been specified in the discussion section:

“Our findings may be generalisable to other general medical journals of similar quality; however the generalisability of our findings to other types of journals or conference abstracts may be limited.” p. 16

“On the basis of our findings, we recommend that all authors routinely report, and all journal editors routinely require, active ingredients to be reported in titles and abstracts.” p. 14

“Another study of abstract reporting quality found that a greater abstract word count was associated with higher reporting quality for structured abstracts [12]. The 150 word limit for abstracts imposed by ABM therefore seems unsuitable. Journals could consider increasing abstract word limits to facilitate higher quality abstract reporting, particularly for NPIs.” p. 15