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Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study

William T Gattrell,[1,2] Sally Hopewell,[3] Kate Young,[4] Paul Farrow,[1] Richard White,[1,2] Elizabeth Wager,[5,6] and Christopher C Winchester[1,7]

[1]Research Evaluation Unit, Oxford PharmaGenesis Ltd, Tubney Warren Barn, Oxford OX13 5QJ

[2]Department of Mechanical Engineering and Mathematical Sciences, Oxford Brookes University, Gipsy Lane, Oxford OX3 0BP

[3]Oxford Clinical Trials Research Unit, University of Oxford, Oxford OX3 7LD

[4]Research Evaluation Unit, Oxford PharmaGenesis Inc., 503 E Washington Avenue, Newtown, PA 18940

[5]Sideview, 19 Station Road, Princes Risborough HP27 9DE

[6]University of Split School of Medicine, Soltanska 2, 21000, Split, Croatia

[7]School of Medicine, Pharmacy and Health, Durham University, University Boulevard, Stockton-on-Tees TS17 6BH

Correspondence to: Dr William Gattrell will.gattrell@pharmagenesis.com

Keywords: Randomised controlled trials, CONSORT, Medical writing, Quality, Peer review

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ABSTRACT

Objectives:

Authors may choose to work with professional medical writers when writing up their research for publication. We examined the relationship between medical writing support and the quality and timeliness of reporting of the results of randomised controlled trials (RCTs).

Design:

Cross-sectional study.

Study sample:

Primary reports of RCTs published in BioMed Central journals from 2000 to 16 July 2014, sub-divided into those with medical writing support (n=110) and without medical writing support (n=123).

Main outcome measures:

Proportion of items that were completely reported from a predefined subset of the Consolidated Standards Of Reporting Trials (CONSORT) checklist (12 items known to be commonly poorly reported), overall acceptance time (from manuscript submission to editorial acceptance) and quality of written English as assessed by peer reviewers. The effect of funding source and publication year was examined.

Results:

The number of articles that completely reported at least 50% of the CONSORT items assessed was higher for those with declared medical writing support (39.1% [43/110 articles]; 95% confidence interval [CI] 29.9 to 48.9%) than for those without (21.1% [26/123 articles]; 95% CI 14.3 to 29.4%). Articles with declared medical writing support were more likely than articles without such support to have acceptable written English (81.1% [43/53 articles]; 95%

CI 67.6 to 90.1% vs 47.9% [23/48 articles]; 95% CI 33.5 to 62.7%). The median time of overall acceptance was longer for articles with declared medical writing support than for those without (167 days [interquartile range 114.5 to 231 days] vs 136 days [interquartile range 77 to 193 days]).

Conclusions:

In this sample of open access journals, declared professional medical writing support was associated with more complete reporting of clinical trial results and higher quality of written English. Medical writing support may play an important role in raising the quality of clinical trial reporting.

Strengths and limitations of this study

- First study to examine the value that professional medical writing support brings to manuscript development across a broad range of journals.
- Used robust methodology and objective measures to assess systematically the quality of reporting of randomised controlled trials in BioMed Central journals.
- In this observational study, the characteristics of the two groups of articles differed in some respects in addition to the involvement of medical writing support.
- Available measurements of timeliness may not correspond to the steps in the manuscript submission process that are the responsibility of professional medical writers.
- Articles that met the inclusion criteria were from 74 different journals, but it remains to be seen whether the findings are applicable to journals other than those published by BioMed Central.

INTRODUCTION

Publication in a peer-reviewed journal remains the gold standard for disclosing clinical study results, but it has been estimated that only about half of biomedical research is published in full, and failure to publish is associated with negative study findings.[1] The pharmaceutical industry in particular has been criticised for incomplete reporting of clinical studies.[2] The complete and transparent reporting of clinical studies is important to allow others to appraise and interpret the results fully.[3] Researchers and clinicians can misjudge the benefits or risks of therapies when study details are not fully disclosed.

Reporting guidelines provide advice on how to disclose research methods and findings.[4] The Consolidated Standards Of Reporting Trials (CONSORT) checklist describes the information that should be included when reporting randomised studies.[5] Although the adoption of the CONSORT checklist by journals has improved the reporting of randomised controlled trials (RCTs), adherence to reporting guidelines remains suboptimal.[6 7] In particular, details of the pre-specified primary outcomes, sample size calculation, randomisation, and allocation concealment are often inadequately disclosed, leaving the reader unable to confirm whether the studies were appropriately planned and conducted.[6 8]

Clinicians understand the importance of disseminating research findings but report lack of time as a major barrier to doing so.[9-11] Authors may enlist the help of professional medical writers, who do not usually meet the criteria for authorship of the article.[12] Such work is undertaken under the direction of the study authors and is subject to strict guidelines.[13 14] Medical writing is not ghostwriting, which occurs when writing contributions are not disclosed in a manuscript.[15] Given the size of the biomedical literature and an estimated prevalence of professional medical writing support of 6–11%,[16 17] it is perhaps surprising that few studies have evaluated the impact of professional medical writing support on the

quality and speed of scientific reporting. In this cross-sectional study we aimed to examine the relationship between declared medical writing support and the quality and timeliness of articles reporting RCTs. Timeliness of acceptance was measured by the time between manuscript submission and editorial acceptance by the journal.

METHODS

Sample selection

We examined the reporting of the results of RCTs of pharmacological interventions published in BioMed Central journals (Box). A pilot study in other journals yielded an insufficiently large sample of articles with declared medical writing support. BioMed Central journals endorse the CONSORT statement and have been used in previous studies of adherence to the CONSORT guidelines.[18] We conducted a search on 16 July 2014 using the BioMed Central website[19] to identify articles that described the results of RCTs. No limits were set for the year of article publication. The search terms used are shown in figure 1.

We divided the articles reporting the results of RCTs into two groups according to whether or not they acknowledged the support of professional medical writers. Articles with declared medical writing support were identified using the search terms 'medical writer', 'medical writing' and 'editorial assistance' (figure 1). The remaining articles were identified as the group without declared medical writing support. To reduce the size of this group in a systematic, unbiased way, articles were selected based on their page number. (In BioMed Central journals, each article is assigned a single page number.) Test searches showed that restricting the page numbers to 1–7 would yield a similar number of articles to that in the group with declared medical writing support.

Eligibility criteria

Eligible studies were primary reports of parallel-group, randomised, interventional trials of pharmacological agents or food supplements. Full articles were reviewed and the presence or absence of declared medical writing support was confirmed. Articles without acknowledgements were excluded. Duplicates, reviews, *post hoc* analyses and study

protocols were also excluded. For the purpose of data collection, the two groups of articles were then combined and sorted alphabetically by title.

Data extraction

The published version of each article was evaluated. We assessed the completeness of reporting of RCTs by scoring articles using a subset of 12 items from the 2010 CONSORT checklist[5] that have previously been shown to be poorly reported.[6 20] Methodological details analysed were the specification of the primary outcome (item 6a), sample size calculation (item 7a), method of generating the random allocation sequence (item 8a), type of randomisation (item 8b), mechanism to implement the allocation sequence (item 9), who generated the allocation sequence (item 10), who was blinded (item 11a), and description of the similarity of interventions (item 11b) (supplementary table 1). The other items that we examined were the publication of a participant flow diagram (item 13), dates defining recruitment and follow-up periods (item 14a), details of trial registration (item 23), and access to the study protocol (item 24). For each article, inclusion of these 12 CONSORT checklist items was assessed independently by two reviewers who were blinded to the objectives of the study. Each item was rated as being completely described, incompletely described, absent, or not applicable. In cases in which there was a discrepancy in the rating, a third reviewer adjudicated.

For overall acceptance time, we extracted the dates of article submission and editorial acceptance. When pre-publication history was available, data were obtained for the time taken for completion of the first round of peer review and for submission of the response to reviewers. Data were also extracted for the quality of written English, as assessed by peer review: the *BMC*-series journals ask reviewers to rate the quality of written English as

"Acceptable", "Needs some language corrections before being published", or "Not suitable for publication unless extensively revised".

We classified articles according to the funding source, as disclosed in the acknowledgements, competing interests, or disclosures section of the manuscripts. Studies were classified as industry-funded if this was declared in the article, or if one or more author had an affiliation with the pharmaceutical industry or other commercial organisation. Articles were classified as part-industry funded if this was stated or if a commercial organisation supplied the study treatment but was not otherwise involved in the study.

Data analysis

To assess the association of adherence to CONSORT guidelines with declared medical writing support, a relative risk (RR) was calculated with 95% confidence intervals (CI) for each of the 12 selected CONSORT items, dichotomised as completely described versus not completely described (incompletely described or absent). Ratings that were not applicable were not included in the analysis. Many articles with medical writing support are funded by industry; hence, a sub-analysis was conducted to examine the association of medical writing support with the reporting quality of industry-sponsored studies. Logistic regression was conducted with medical writing support as the independent variable, complete description of at least 50% of the items as the dependent variable and year as a co-variable. No formal sample size or power calculation was performed: the size of the study was determined by the number of articles with medical writing support in the study sample. Statistical analysis was conducted using STATA (version 13). Medians and interquartile ranges (IQRs) were calculated using Microsoft Excel.

Text box

About BioMed Central

Founded in 2000, BioMed Central is the largest open access science publisher.

BioMed Central publishes over 290 peer-reviewed journals, which span many areas of biology and medicine, with impact factors ranging from 0.4 to 10.5.

To date, approximately 250 000 articles have been published by BioMed Central.

For some BioMed Central journals, pre-publication history is available, including peer reviewers' comments and the dates of submission, peer review, and editorial acceptance.

RESULTS

Characteristics of the articles assessed

Our initial electronic search identified 305 potentially relevant articles reporting the results of RCTs with declared medical writing support (figure 1). Following manual review, 110 articles from 44 different journals were confirmed as eligible for inclusion in the group of articles with medical writing support. There were 10 688 potentially relevant articles without declared medical writing support; after filtering on page number, 387 articles remained. After manual review, 123 articles from 57 different journals met the eligibility criteria for inclusion as RCT reports without declared medical writing support. For both groups, most of the excluded publications were study protocols or secondary reports of RCTs. Overall, articles that met the inclusion criteria were from 74 different journals.

Articles with declared medical writing support described studies with a higher median number of randomised patients than articles without this support (159 patients [IQR 65.75 to 407.75 patients] vs 43 patients [IQR 21 to 82 patients]) (table 1). Almost all articles with declared medical writing support were industry funded (98.2%). In contrast, only 31.7% of articles without medical writing support were funded by industry. The first identified article without declared medical writing support was published in 2001. The first article with declared medical writing support was published in 2005, and there was an increase in the number of declared medical writing support over the study period (supplementary figure 1).

Table 1 General characteristics of the included studies

	Medical writing support (n=110)	**No medical writing support (n=123)**
Number of journals that articles were published in	44	57
Number of authors, median (interquartile range)	7 (5–9)	6 (4–8)
Articles published on behalf of a study group	12 (10.9%)	4 (3.3%)
Number of patients randomised to study, median (interquartile range)	159 (65.75–407.75)	43 (21–82)
Year of publication		
2001–2004	0	17 (13.8%)
2005–2007	12 (10.9%)	25 (20.3%)
2008–2010	31 (28.2%)	34 (27.6%)
2011–2014	67 (60.9%)	47 (38.2%)
Funding source		
Industry	108 (98.2%)	39 (31.7%)
Part-industry	2 (1.8%)	23 (18.7%)
Non-industry	0	61 (49.6%)

Completeness of reporting

For six of the twelve CONSORT items assessed, a higher rate of complete reporting was observed in articles with acknowledged medical writing support than in those without (figure 2). These were specification of the primary outcome (RR 1.77; 95% CI 1.47 to 2.13), sample size calculation (RR 1.39; 95% CI 1.10 to 1.75), type of randomisation (RR 2.03; 95% CI 1.17 to 3.53), publication of a participant flow diagram (RR 1.96; 95% CI 1.48 to 2.61), provision of dates defining recruitment and follow-up (RR 2.04; 95% CI 1.32 to 3.17), and details of trial registration (RR 1.64; 95% CI 1.34 to 2.01). RR could not be calculated for item 10 (who generated the allocation sequence) because it was fully described only in articles with acknowledged medical writing support. For the other five items, there was no association between medical writing support and completeness of reporting.

The proportion of articles that completely reported at least 50% of the CONSORT items assessed was higher for those with declared medical writing support than for those without declared medical writing support (39.1% [43/110 articles]; 95% CI 29.9 to 48.9% vs 21.1% [26/123 articles]; 95% CI 14.3 to 29.4%). In the sub-analysis looking at industry-funded articles, those with declared medical writing support were more than twice as likely as those articles without declared medical writing support to report at least 50% of studied items completely (38.0% [41/108 articles]; 95% CI 28.9 to 47.8% vs 17.9% [7/39 articles]; 95% CI 8.1 to 34.1%). When looking at articles without acknowledged medical writing support, there was no association between funding source and the completeness of reporting.

A logistic regression analysis showed that year of publication was associated with quality of reporting (odds ratio 1.18; 95% CI 1.06 to 1.32). Thus, the odds of reporting at least 50% of items completely increased every year by 18%. Taking into account publication year, the odds ratio of reporting at least 50% of CONSORT items completely for articles with declared

medical writing support was 1.88 (95% CI 1.03 to 3.42). Supplementary figure 2 shows the mean proportion of complete items stratified by year of publication and the presence or absence of medical writing support. For each year, the mean proportion of completely reported items was higher for articles with medical writing support than for those without.

Quality of written English

Articles with declared medical writing support were more likely than those without to have been rated by all the reviewers as having acceptable written English during peer review (81.1% [43/53 articles]; 95% CI 67.6 to 90.1% vs 47.9% [23/48 articles]; 95% CI 33.5 to 62.7%).

Time from manuscript submission to editorial acceptance

Overall, the median acceptance time was 31 days longer for articles with declared medical writing support than for those without (167 days [IQR 114.5 to 231 days] vs 136 days [IQR 77 to 193 days]). For both study groups, the median number of versions submitted was three. Considering the subgroup of industry-funded studies with and without declared medical writing support (n=107 and n=39 articles, respectively), those with declared medical writing support had a longer median acceptance time than those without (169 days [IQR 113 to 232 days] vs 104 days [IQR 77 to 180 days]).

To identify possible reasons for this delay in acceptance, the time taken for different steps in manuscript processing was analysed for articles with this information. Median time from submission to completion of peer review and median time to respond to reviewers were longer for articles with medical writing support than for those without (supplementary table 2). The time from response to reviewers to editorial acceptance was similar for both

groups of articles. This pattern remained when the analysis was restricted to industry-funded articles (supplementary table 3).

DISCUSSION

Declared professional medical writing support was associated with improved completeness of reporting in our observational study of reports of RCTs published in a series of open access journals between 2000 and 2014. In the absence of declared medical writing support, there was no difference in the completeness of reporting between articles reporting industry-funded trials and non- and part-industry-funded trials. Completeness of reporting was enhanced across a range of important items from the CONSORT checklist, including the specification of the primary outcome, and details of the sample size calculation and randomisation. The complete reporting of the design and conduct of clinical studies is at the heart of evidence-based medicine. The effects of interventions can be exaggerated or underestimated in studies with poor methodology, and researchers can assess the likelihood of bias only if the methods and results are completely reported.[21 22] Articles with declared medical writing support were also associated with better quality of written English than those without. There are sound reasons to believe that the involvement of professional medical writers improves the overall quality of articles. Medical writers specialise in developing peer-reviewed manuscripts and other scientific documents, and commonly receive training in Good Publication Practice.[23]

The findings of our study also suggest that overall compliance with CONSORT guidelines is lacking. Even with professional medical writing support, fewer than half of the articles reported at least 50% of studied CONSORT items completely. As well as authors, both peer reviewers and journal editors have responsibility for ensuring that articles adhere to reporting guidelines. However, peer reviewers often fail to notice important deficiencies in the reporting of RCTs.[18] In fact, peer reviewers may not understand the importance of checking the compliance of articles with CONSORT guidelines, possibly as a result of

insufficiently explicit instructions regarding their role.[24] From our own experience, checking an article for compliance with the full CONSORT checklist would take approximately 1 hour. We would suggest that this is a specialized task that could be undertaken by a designated member of journal staff, or even by a professional medical writer.

This study looked at the quality of published articles in a real-life situation. Because this was not a randomised study, the characteristics of the two groups of articles differ in some respects in addition to the involvement of medical writing support. The key differences between the two groups of articles were that those with declared medical writing support were almost exclusively sponsored by industry and were published more recently than those written without medical writing support. However, it seems unlikely that the results of this study can be attributed to these differences between the two groups of articles. Thus, in the subset of industry-funded trials, completeness of reporting was even more strongly associated with medical writing support. Furthermore, in each year of publication, the mean proportion of complete items was higher for articles with medical writing support than for those without. Articles with declared medical writing support were associated with a slightly longer overall acceptance time than articles without this support. One limitation of this assessment is that the measure of timeliness may not correspond to steps in the submission process that are the responsibility of the medical writer. The delay in overall acceptance was attributable to additional time taken for peer review and for the authors to respond to reviewers. Articles that declared medical writing support tended to describe larger trials than those without, and had more authors, suggesting that these articles may have reported more complex research and therefore taken longer to review or, possibly, underwent greater scrutiny by peer reviewers. Likewise, queries from peer reviewers may be more complicated for articles with medical writing support than for those without.

The classification of articles in our study was based on the declaration of medical writing involvement, and we have assumed that the enhanced quality of reporting can be attributed to this support. The importance of acknowledging medical writing support is stated in guidelines on Good Publication Practice and, according to the editorial policy of BioMed Central, medical writing support should be acknowledged explicitly.[14 25] Although we cannot rule out the possibility that some articles were written with undeclared writing support, this would tend to underestimate the true differences between the two groups. Finally, the articles that met the inclusion criteria for our study were from 74 different journals, but it remains to be seen whether our findings are applicable to journals other than those published by BioMed Central. The articles included in this study may not be representative of those published in journals that do not endorse the CONSORT checklist (i.e. the effect of medical writing support may be increased if authors do not receive guidance from the journal). Conversely, the effect of medical writing support may be reduced in journals that ensure compliance with CONSORT criteria.

A systematic review published in 2003 found that there was insufficient research to assess the effects of professional writing assistance on biomedical publishing.[26] Only one other study has evaluated the association of declared medical writing support and the completeness of reporting.[20] This analysis was restricted to a single journal in which there were very few non-industry-sponsored studies and the overall completeness of reporting was high; although articles that declared professional medical writers were more likely to comply with the CONSORT criteria, the effect was small. A study of articles published in the *Dutch Journal of Medicine* found that editing for scientific content and written English, tasks that are often undertaken by medical writers, significantly improved the style and readability of manuscripts.[27] It has previously been suggested that, in addition to raising the standard of publications, professional medical writer involvement can speed up the publication

process;[13] however, there is limited evidence to demonstrate the acceleration of manuscript acceptance with medical writing support [28 29] and, in the current study, overall acceptance time was slightly longer in the group with medical writing support.

Clinical trials can help to advance the treatment of patients only if the methods and results are fully disclosed. The reporting of industry-sponsored studies appears to be improving over time,[30] and a recent study showed that industry-funded trials were more likely to comply with legal reporting obligations than trials funded by government or academic institutions.[31] Our results suggest that the enhanced reporting seen in industry-funded trials may be attributable to professional medical writing support. Even so, when only approximately half of research is published in full and many publications do not disclose important information, much research effort is wasted.[32] In fact, it has been proposed that professional medical writing support should be used to address the backlog of unreported clinical study results.[33] The results of the present study suggest that this support could also improve the quality of RCT reporting. Medical writing support is often funded by industry and, as a result, has sometimes attracted controversy.[34 35] There is no place for ghostwriting (i.e. the unacknowledged use of professional medical writers) in manuscript development. According to the results of surveys, the overwhelming majority of authors (84–88%) valued the assistance provided by professional medical writers, in particular in editing manuscripts and ensuring conformity with reporting guidelines such as CONSORT.[36 37] Accordingly, the legitimate role that medical writers can play is acknowledged in guidelines on Good Publication Practice.[14]

Conclusions

There remains a need to improve the quality of reporting of clinical studies. The disclosure of important information regarding clinical studies, which is needed when determining the

validity and generalisability of findings, may be enhanced with professional medical writing support.

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Contributors WTG and CCW were involved in the design, implementation, and analysis of the study, and in drafting the manuscript. SH, PF, RW, and EW were involved in the design and analysis of the study, and commented on the manuscript. KY conducted the statistical analysis of the study and commented on the manuscript. WTG is the guarantor of the study.

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Competing interests All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that: WTG, PF, RW, and CCW are medical communication professionals employed by Oxford PharmaGenesis. KY is a former employee of Oxford PharmaGenesis. PF, RW, and CCW are shareholders of Oxford PharmaGenesis. CCW holds shares in AstraZeneca and Shire Pharmaceuticals. SH is a member of the CONSORT group. EW is the owner of Sideview, which provides training and consultancy in medical writing, and has previously worked as a medical writer.

Data sharing The full dataset is available on request from the corresponding author (will.gattrell@pharmagenesis.com)

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Figure 1 Overview of the study design.

RCTs, randomised controlled trials.

The terms TIAB and PG allow searches to be specified based on title/abstract and article page number, respectively.

Figure 2 Differences in the reporting of CONSORT items between articles with and without acknowledged medical writing support.

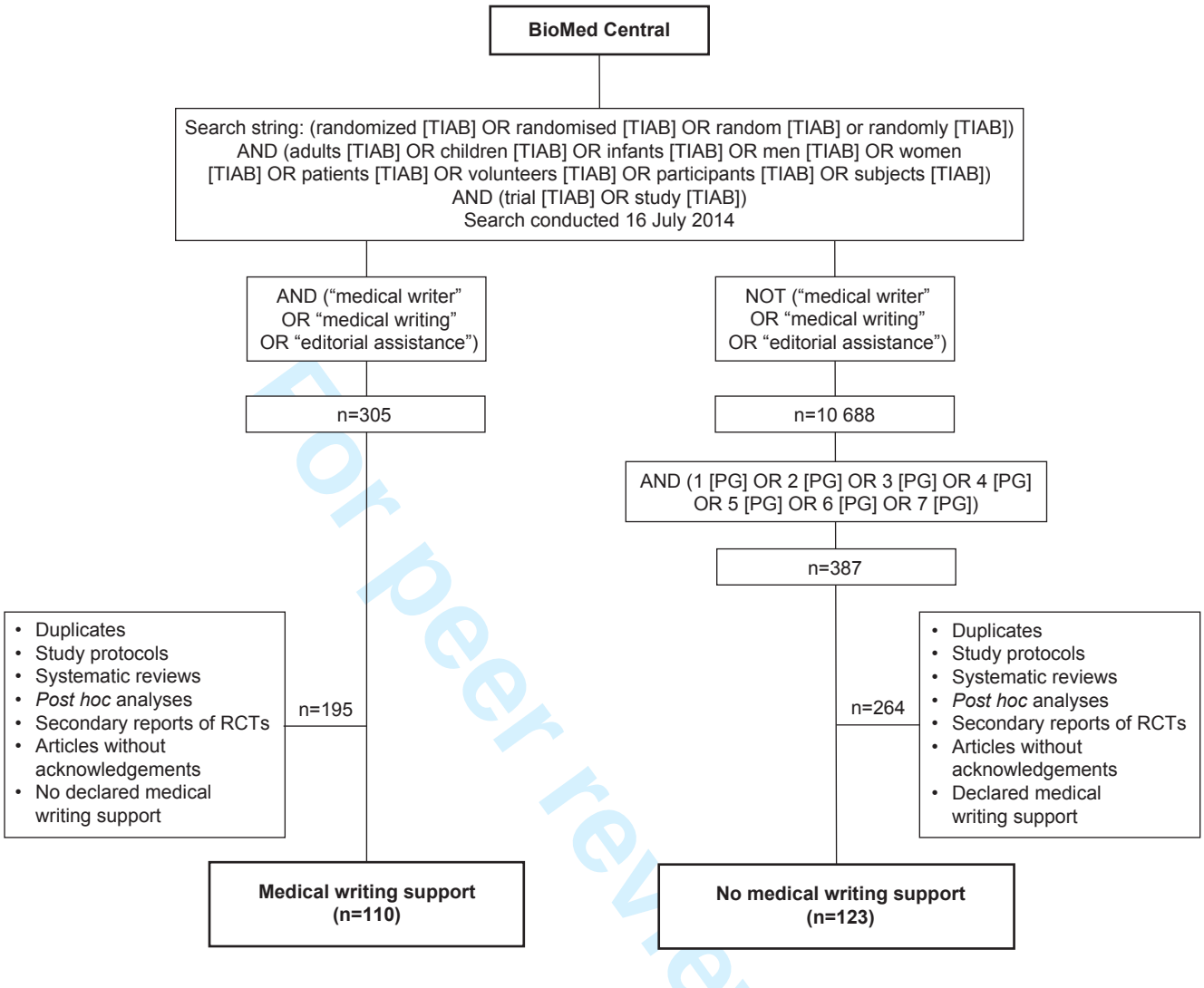
CI, confidence interval; CONSORT, Consolidated Standards Of Reporting Trials; NA, not applicable.

*Relative risk could not be calculated for item 10 because all articles in the group without acknowledged medical writing support were assessed as having been incompletely described.

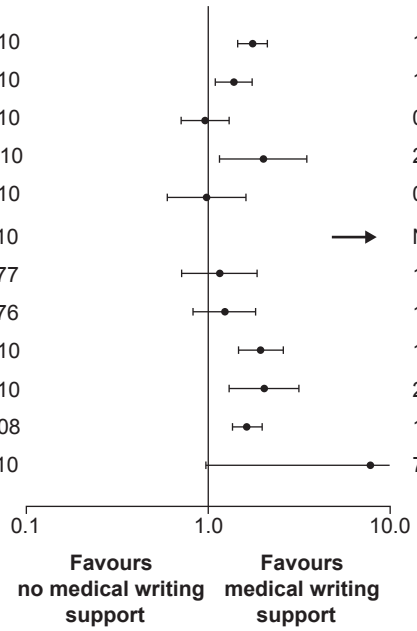
Supplementary figure 1 Year of article publication, stratified by medical writing support.

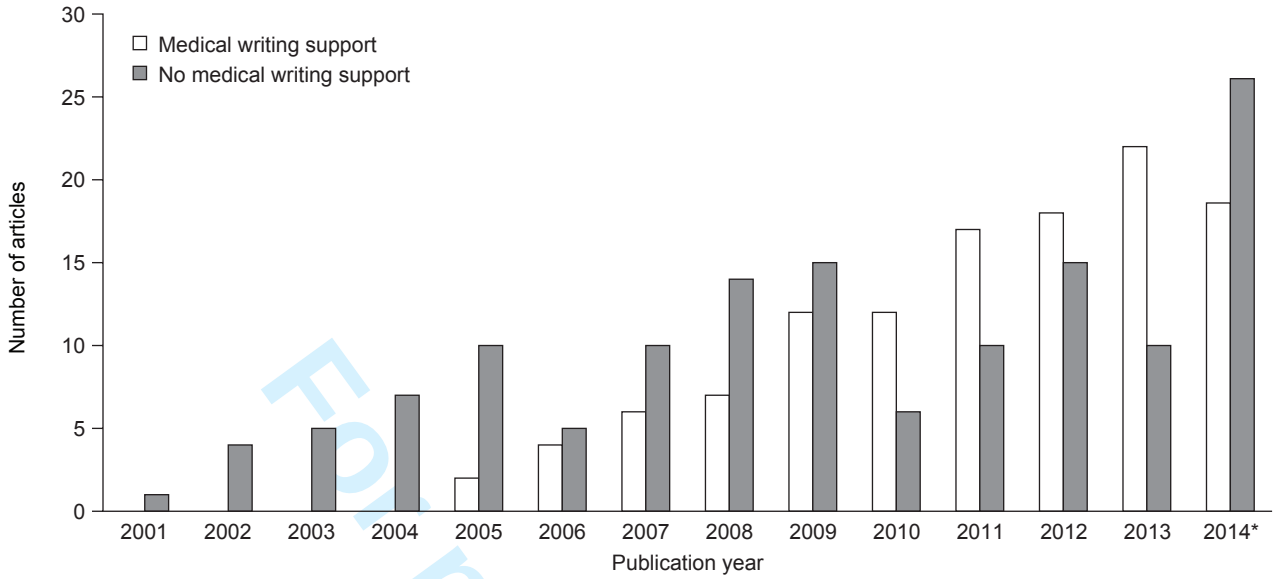
*Adjusted to number of articles per 12 months.

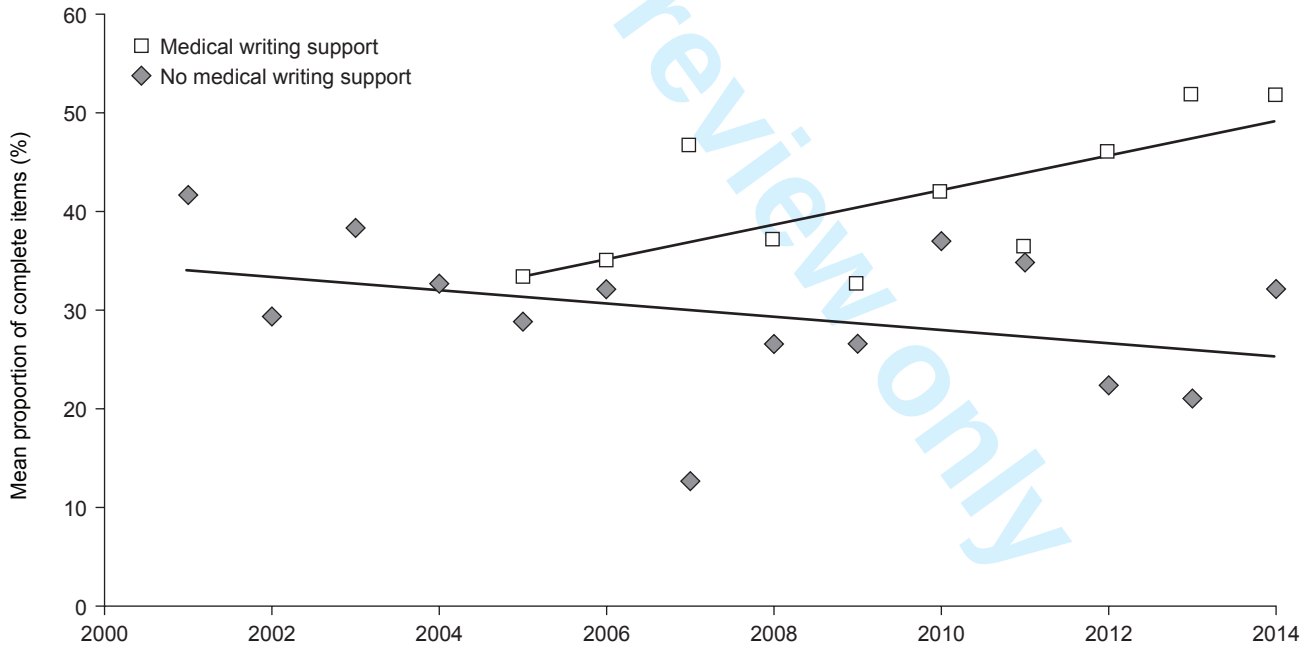
Supplementary figure 2 Mean proportion of complete items, stratified by year of publication and medical writing support.



CONSORT item (number)	Events/total: Non-medical writer	Events/total: Medical writer	Relative risk (95% CI)
Specification of the primary outcome (6a)	62/123	98/110	1.77 (1.47 to 2.13)
Sample size calculation (7a)	58/123	72/110	1.39 (1.10 to 1.75)
Method of generating the random allocation sequence (8a)	51/123	44/110	0.97 (0.72 to 1.32)
Type of randomisation (8b)	16/123	29/110	2.03 (1.17 to 3.53)
Mechanism to implement the allocation sequence (9)	26/123	23/110	0.99 (0.60 to 1.63)
Who generated the allocation sequence (10)	0/123	5/110	NA*
Who was blinded (11a)	28/114	22/77	1.16 (0.72 to 1.88)
Description of the similarity of interventions (11b)	34/107	30/76	1.24 (0.84 to 1.84)
Publication of a participant flow diagram (13)	41/123	72/110	1.96 (1.48 to 2.61)
Provision of dates defining recruitment and follow-up (14a)	23/123	42/110	2.04 (1.32 to 3.17)
Details of trial registration (23)	60/122	87/108	1.64 (1.34 to 2.01)
Access to the study protocol (24)	1/123	7/110	7.83 (0.98 to 62.62)







Supplementary table 1 Criteria used for assessing the completeness of reporting, based on the 2010 CONSORT checklist

Definitions used to assess the completeness of reporting (CONSORT item and number)
Specification of the primary outcome (6a) *Complete:* primary/main outcome defined and fully described *Incomplete:* outcome present, but not defined as such
Sample size calculation (7a) *Complete:* method of power calculation included *Incomplete:* planned sample size mentioned but values or methods not reported
Method of generating random allocation sequence (8a) *Complete:* specific method of randomisation given (e.g. random number table) *Incomplete:* non-specific method given (e.g. "automated randomisation system")
Type of randomisation (8b) *Complete:* full details of randomisation given *Incomplete:* type of randomisation described but no details given
Mechanism to implement allocation sequence (9) *Complete:* both the mechanism used and how the allocation was concealed were present *Incomplete*: either the mechanism used or how the allocation was concealed were described
Who generated the allocation sequence (10) *Complete*: description of who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions *Incomplete*: one or two of these described

Definitions used to assess the completeness of reporting (CONSORT item and number)
Who was blinded (11a)
Complete: blinding status of all groups (participants/investigators/assessors) defined
Incomplete: blinding status of one or more groups described
Absent: stated as "single-blind" or "double-blind" only
NA: open-label study
Description of the similarity of interventions (11b)
Complete: relevant similarities described (appearance/taste/smell/volume/method of administration)
Incomplete: described only as 'identical', 'matching' or 'corresponding' etc.
NA: treatment defined as open label or interventions stated as too dissimilar to blind
Publication of a participant flow diagram (13)
Complete: diagram showed number of patients enrolled, numbers excluded and lost to follow-up, and reasons for exclusion or loss to follow-up
Incomplete: diagram included patient flow and numbers enrolled but was missing some information
Dates defining recruitment and follow-up periods (14a)
Complete: period of study/recruitment and follow-up period fully defined
Incomplete: only one of the above periods defined
Details of trial registration (23)
Complete: registration number stated in text
NA: study conducted before the International Committee of Medical Journal Editors recommendation that clinical trials should be registered at or before the time of first patient enrolment
Access to the study protocol (24)
Complete: protocol number and location/registry stated

For the full list of items on the CONSORT checklist, see: http://www.consort-statement.org/

CONSORT, Consolidated Standards Of Reporting Trials; NA, not applicable.

Supplementary table 2 Time to complete different stages of article processing

Duration, days	Medical writing support (n=55)	No medical writing support (n=64)
Peer review	87 (55–122)	55 (35.5–86.75)
Responding to reviewers	60 (35–83)	32 (17–58.25)
Editorial acceptance	49 (23–96)	50 (29.75–98.75)
Submission to editorial acceptance	206 (164–264)	162.5 (104.25–217.5)

Data are presented as median (interquartile range).

Supplementary table 3 Time to complete different stages of article processing (industry-funded articles only)

Duration, days	**Medical writing support (n=55)**	**No medical writing support (n=18)**
Peer review	87 (55–122)	50.5 (37.75–74.25)
Responding to reviewers	60 (35–83)	28 (13–67.75)
Editorial acceptance	49 (23–96)	50 (39.5–113.25)
Submission to editorial acceptance	206 (164–264)	161 (103.5–270.25)

Data are presented as median (interquartile range).

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page number
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2–3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7–8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	7–8
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8–9
Bias	9	Describe any efforts to address potential sources of bias	9
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9
		(*b*) Describe any methods used to examine subgroups and interactions	9
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, explain how loss to follow-up was addressed	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11 and Table 1
		(b) Indicate number of participants with missing data for each variable of interest	11–13
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over time	12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted	11–13

		estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	13–14
Discussion			
Key results	18	Summarise key results with reference to study objectives	16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16–18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16–19
Generalisability	21	Discuss the generalisability (external validity) of the study results	16–19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study

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Secondary Subject Heading:	Communication
Keywords:	Randomised controlled trials, CONSORT, Medical writing, Quality, Peer review

Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study

William T Gattrell,[1,2] Sally Hopewell,[3] Kate Young,[4] Paul Farrow,[1] Richard White,[1,2] Elizabeth Wager,[5,6] and Christopher C Winchester[1,7]

[1]Research Evaluation Unit, Oxford PharmaGenesis Ltd, Tubney Warren Barn, Oxford OX13 5QJ

[2]Department of Mechanical Engineering and Mathematical Sciences, Oxford Brookes University, Gipsy Lane, Oxford OX3 0BP

[3]Oxford Clinical Trials Research Unit, University of Oxford, Oxford OX3 7LD

[4]Research Evaluation Unit, Oxford PharmaGenesis Inc., 503 E Washington Avenue, Newtown, PA 18940

[5]Sideview, 19 Station Road, Princes Risborough HP27 9DE

[6]University of Split School of Medicine, Soltanska 2, 21000, Split, Croatia

[7]School of Medicine, Pharmacy and Health, Durham University, University Boulevard, Stockton-on-Tees TS17 6BH

Correspondence to: Dr William Gattrell will.gattrell@pharmagenesis.com

Keywords: Randomised controlled trials, CONSORT, Medical writing, Quality, Peer review

Word count: 3784

ABSTRACT

Objectives:

Authors may choose to work with professional medical writers when writing up their research for publication. We examined the relationship between medical writing support and the quality and timeliness of reporting of the results of randomised controlled trials (RCTs).

Design:

Cross-sectional study.

Study sample:

Primary reports of RCTs published in BioMed Central journals from 2000 to 16 July 2014, sub-divided into those with medical writing support (n=110) and without medical writing support (n=123).

Main outcome measures:

Proportion of items that were completely reported from a predefined subset of the Consolidated Standards Of Reporting Trials (CONSORT) checklist (12 items known to be commonly poorly reported), overall acceptance time (from manuscript submission to editorial acceptance) and quality of written English as assessed by peer reviewers. The effect of funding source and publication year was examined.

Results:

The number of articles that completely reported at least 50% of the CONSORT items assessed was higher for those with declared medical writing support (39.1% [43/110 articles]; 95% confidence interval [CI] 29.9 to 48.9%) than for those without (21.1% [26/123 articles]; 95% CI 14.3 to 29.4%). Articles with declared medical writing support were more likely than articles without such support to have acceptable written English (81.1% [43/53 articles]; 95%

CI 67.6 to 90.1% vs 47.9% [23/48 articles]; 95% CI 33.5 to 62.7%). The median time of overall acceptance was longer for articles with declared medical writing support than for those without (167 days [interquartile range 114.5 to 231 days] vs 136 days [interquartile range 77 to 193 days]).

Conclusions:

In this sample of open access journals, declared professional medical writing support was associated with more complete reporting of clinical trial results and higher quality of written English. Medical writing support may play an important role in raising the quality of clinical trial reporting.

Strengths and limitations of this study

- First study to examine the value that professional medical writing support brings to manuscript development across a broad range of journals.
- Used robust methodology and objective measures to assess systematically the quality of reporting of randomised controlled trials in BioMed Central journals.
- In this observational study, the characteristics of the two groups of articles differed in some respects in addition to the involvement of medical writing support.
- Available measurements of timeliness may not correspond to the steps in the manuscript submission process that are the responsibility of professional medical writers.
- Articles that met the inclusion criteria were from 74 different journals, but it remains to be seen whether the findings are applicable to journals other than those published by BioMed Central.

INTRODUCTION

Publication in a peer-reviewed journal remains the gold standard for disclosing clinical study results, but it has been estimated that only about half of biomedical research is published in full, and failure to publish is associated with negative study findings.[1] The pharmaceutical industry in particular has been criticised for incomplete reporting of clinical studies.[2] The complete and transparent reporting of clinical studies is important to allow others to appraise and interpret the results fully.[3] Researchers and clinicians can misjudge the benefits or risks of therapies when study details are not fully disclosed.

Reporting guidelines provide advice on how to disclose research methods and findings.[4] The Consolidated Standards Of Reporting Trials (CONSORT) checklist describes the information that should be included when reporting randomised studies.[5] Although the adoption of the CONSORT checklist by journals has improved the reporting of randomised controlled trials (RCTs), adherence to reporting guidelines remains suboptimal.[6 7] In particular, details of the pre-specified primary outcomes, sample size calculation, randomisation, and allocation concealment are often inadequately disclosed, leaving the reader unable to confirm whether the studies were adequately planned and conducted.[6 8]

Clinicians understand the importance of disseminating research findings but report lack of time as a major barrier to doing so.[9-11] Authors may enlist the help of professional medical writers, who do not usually meet the criteria for authorship of the article.[12] Such work is undertaken under the direction of the study authors and is subject to strict guidelines.[13 14] Medical writing is not ghostwriting, which occurs when writing contributions are not disclosed in a manuscript.[15] Given the size of the biomedical literature and an estimated prevalence of professional medical writing support of 6–11%,[16 17] it is perhaps surprising that few studies have evaluated the impact of professional medical writing support on the

quality and speed of scientific reporting. In this cross-sectional study we aimed to examine the relationship between declared medical writing support and the quality and timeliness of articles reporting RCTs. Timeliness of acceptance was measured by the time between manuscript submission and editorial acceptance by the journal; manuscript preparation time was not assessed.

METHODS

Sample selection

We examined the reporting of the results of RCTs of pharmacological interventions published in BioMed Central journals (Text Box). A pilot study in other journals yielded an insufficiently large sample of articles with declared medical writing support. BioMed Central journals endorse the CONSORT statement and have been used in previous studies of adherence to the CONSORT guidelines.[18] We conducted a search on 16 July 2014 using the BioMed Central website[19] to identify articles that described the results of RCTs. No limits were set for the year of article publication. The search terms used are shown in figure 1.

We divided the articles reporting the results of RCTs into two groups according to whether or not they acknowledged the support of professional medical writers. Articles with declared medical writing support were identified using the search terms ‘medical writer’, ‘medical writing’ and ‘editorial assistance’ (figure 1). The remaining articles were identified as the group without declared medical writing support. To reduce the size of this group in a systematic, unbiased way, articles were selected based on their page number. (In BioMed Central journals, each article is assigned a single page number.) Test searches showed that restricting the page numbers to 1–7 would yield a similar number of articles to that in the group with declared medical writing support.

Eligibility criteria

All primary reports of parallel-group, randomised trials of pharmacological and food supplement interventions were included. Full articles were reviewed and the presence or absence of declared medical writing support was confirmed. Articles without

acknowledgements were excluded. Duplicates, reviews, *post hoc* analyses and study protocols were also excluded. For the purpose of data collection, the two groups of articles were then combined and sorted alphabetically by title.

Data extraction

The published version of each article was evaluated. We assessed the completeness of reporting of RCTs by scoring articles using a subset of 12 items from the 2010 CONSORT checklist[5] that have previously been shown to be poorly reported.[6 20] Methodological details analysed were the specification of the primary outcome (item 6a), sample size calculation (item 7a), method of generating the random allocation sequence (item 8a), type of randomisation (item 8b), mechanism to implement the allocation sequence (item 9), who generated the allocation sequence (item 10), who was blinded (item 11a), and description of the similarity of interventions (item 11b) (supplementary table 1). The other items that we examined were the publication of a participant flow diagram (item 13), dates defining recruitment and follow-up periods (item 14a), details of trial registration (item 23), and access to the study protocol (item 24). For each article, inclusion of these 12 CONSORT checklist items was assessed independently by two reviewers who were blinded to the objectives of the study. Each item was rated as being completely described, incompletely described, absent, or not applicable. In cases in which there was a discrepancy in the rating, a third reviewer adjudicated.

For overall acceptance time, we extracted the dates of article submission and editorial acceptance. When pre-publication history was available, data were obtained for the time taken for completion of the first round of peer review and for submission of the response to reviewers. Data were also extracted for the quality of written English, as assessed by peer review: the *BMC*-series journals ask reviewers to rate the quality of written English as

"Acceptable", "Needs some language corrections before being published", or "Not suitable for publication unless extensively revised".

We classified articles according to the funding source, as disclosed in the acknowledgements, competing interests, or disclosures section of the manuscripts. Studies were classified as industry-funded if this was declared in the article, or if one or more author had an affiliation with the pharmaceutical industry or other commercial organisation. Articles were classified as part-industry funded if this was stated or if a commercial organisation supplied the study treatment but was not otherwise involved in the study.

Data analysis

To assess the association of adherence to CONSORT guidelines with declared medical writing support, a relative risk (RR) was calculated with 95% confidence intervals (CI) for each of the 12 selected CONSORT items, dichotomised as completely described versus not completely described (incompletely described or absent). Ratings that were not applicable were not included in the analysis. Many articles with medical writing support are funded by industry; hence, a sub-analysis was conducted to examine the association of medical writing support with the reporting quality of industry-sponsored studies. Logistic regression was conducted with medical writing support as the independent variable, complete description of at least 50% of the items as the dependent variable and year as a co-variable. No formal sample size or power calculation was performed: the size of the study was determined by the number of articles with medical writing support in the study sample. Statistical analysis was conducted using STATA (version 13). Medians and interquartile ranges (IQRs) were calculated using Microsoft Excel.

Text box

About BioMed Central

Founded in 2000, BioMed Central is the largest open access science publisher.

BioMed Central publishes over 290 peer-reviewed journals, which span many areas of biology and medicine, with impact factors ranging from 0.4 to 10.5.

To date, approximately 250 000 articles have been published by BioMed Central.

For some BioMed Central journals, pre-publication history is available, including peer reviewers' comments and the dates of submission, peer review, and editorial acceptance.

RESULTS

Characteristics of the articles assessed

Our initial electronic search identified 305 potentially relevant articles reporting the results of RCTs with declared medical writing support (figure 1). Following manual review, 110 articles from 44 different journals were confirmed as eligible for inclusion in the group of articles with medical writing support. The distribution of the search terms used to identify medical writing support was: 'medical writer' (12.7%); 'medical writing' (43.6%); 'editorial assistance' (21.8%) and 'medical writing' and 'editorial assistance' (21.8%). There were 10 688 potentially relevant articles without declared medical writing support; after filtering on page number, 387 articles remained. After manual review, 123 articles from 57 different journals met the eligibility criteria for inclusion as RCT reports without declared medical writing support. For both groups, most of the excluded publications were study protocols or secondary reports of RCTs. Overall, articles that met the inclusion criteria were from 74 different journals.

Articles with declared medical writing support described studies with a higher median number of randomised patients than articles without this support (159 patients [IQR 65.75 to 407.75 patients] vs 43 patients [IQR 21 to 82 patients]) (table 1). Almost all articles with declared medical writing support were industry funded (98.2%). In contrast, only 31.7% of articles without medical writing support were funded by industry. The first identified article without declared medical writing support was published in 2001. The first article with declared medical writing support was published in 2005, and there was an increase in the number of declared medical writing support over the study period (supplementary figure 1).

Table 1 General characteristics of the included studies

	Medical writing support (n=110)	**No medical writing support (n=123)**
Number of journals that articles were published in	44	57
Number of authors, median (interquartile range)	7 (5–9)	6 (4–8)
Articles published on behalf of a study group	12 (10.9%)	4 (3.3%)
Number of patients randomised to study, median (interquartile range)	159 (65.75–407.75)	43 (21–82)
Year of publication		
2001–2004	0	17 (13.8%)
2005–2007	12 (10.9%)	25 (20.3%)
2008–2010	31 (28.2%)	34 (27.6%)
2011–2014	67 (60.9%)	47 (38.2%)
Funding source		
Industry	108 (98.2%)	39 (31.7%)
Part-industry	2 (1.8%)	23 (18.7%)
Non-industry	0	61 (49.6%)

Completeness of reporting

For six of the twelve CONSORT items assessed, a higher rate of complete reporting was observed in articles with acknowledged medical writing support than in those without (figure 2). These were specification of the primary outcome (RR 1.77; 95% CI 1.47 to 2.13), sample size calculation (RR 1.39; 95% CI 1.10 to 1.75), type of randomisation (RR 2.03; 95% CI 1.17 to 3.53), publication of a participant flow diagram (RR 1.96; 95% CI 1.48 to 2.61), provision of dates defining recruitment and follow-up (RR 2.04; 95% CI 1.32 to 3.17), and details of trial registration (RR 1.64; 95% CI 1.34 to 2.01). RR could not be calculated for item 10 (who generated the allocation sequence) because it was fully described only in articles with acknowledged medical writing support. For the other five items, there was no association between medical writing support and completeness of reporting.

A sensitivity analysis for completeness of reporting is shown in supplementary table 2. The proportion of articles that completely reported at least 50% of the CONSORT items assessed was higher for those with declared medical writing support than for those without declared medical writing support (39.1% [43/110 articles]; 95% CI 29.9 to 48.9% vs 21.1% [26/123 articles]; 95% CI 14.3 to 29.4%). In the sub-analysis looking at industry-funded articles, those with declared medical writing support were more than twice as likely as those articles without declared medical writing support to report at least 50% of studied items completely (38.0% [41/108 articles]; 95% CI 28.9 to 47.8% vs 17.9% [7/39 articles]; 95% CI 8.1 to 34.1%). When looking at articles without acknowledged medical writing support, there was no association between funding source and the completeness of reporting.

A logistic regression analysis showed that year of publication was associated with quality of reporting (odds ratio 1.18; 95% CI 1.06 to 1.32). Thus, the odds of reporting at least 50% of items completely increased every year by 18%. Taking into account publication year, the

odds ratio of reporting at least 50% of CONSORT items completely for articles with declared medical writing support was 1.88 (95% CI 1.03 to 3.42). Supplementary figure 2 shows the mean proportion of complete items stratified by year of publication and the presence or absence of medical writing support. For each year, the mean proportion of completely reported items was higher for articles with medical writing support than for those without.

Quality of written English

Articles with declared medical writing support were more likely than those without to have been rated by all the reviewers as having acceptable written English during peer review (81.1% [43/53 articles]; 95% CI 67.6 to 90.1% vs 47.9% [23/48 articles]; 95% CI 33.5 to 62.7%). The proportion of articles with the corresponding author having an affiliation from a country where English was the first language was similar for both groups: 49.1% and 50.4%, respectively, for articles with and without medical writing support.

Time from manuscript submission to editorial acceptance

Overall, the median acceptance time was 31 days longer for articles with declared medical writing support than for those without (167 days [IQR 114.5 to 231 days] vs 136 days [IQR 77 to 193 days]). For both study groups, the median number of versions submitted was three. Considering the subgroup of industry-funded studies with and without declared medical writing support (n=107 and n=39 articles, respectively), those with declared medical writing support had a longer median acceptance time than those without (169 days [IQR 113 to 232 days] vs 104 days [IQR 77 to 180 days]).

To identify possible reasons for this delay in acceptance, the time taken for different steps in manuscript processing was analysed for articles with this information. Median time from submission to completion of peer review and median time to respond to reviewers were

longer for articles with medical writing support than for those without (supplementary table 3). The time from response to reviewers to editorial acceptance was similar for both groups of articles. This pattern remained when the analysis was restricted to industry-funded articles (supplementary table 4).

DISCUSSION

Declared professional medical writing support was associated with improved completeness of reporting in our observational study of reports of RCTs published in a series of open access journals between 2000 and 2014. In the absence of declared medical writing support, there was no difference in the completeness of reporting between articles reporting industry-funded trials and non- and part-industry-funded trials. Completeness of reporting was enhanced across a range of important items from the CONSORT checklist, including the specification of the primary outcome, and details of the sample size calculation and randomisation. The complete reporting of the design and conduct of clinical studies is at the heart of evidence-based medicine. The effects of interventions can be exaggerated or underestimated in studies with poor methodology, and researchers can assess the likelihood of bias only if the methods and results are completely reported.[21 22] Articles with declared medical writing support were also associated with better quality of written English than those without. There are sound reasons to believe that the involvement of professional medical writers improves the overall quality of articles. Medical writers specialise in developing peer-reviewed manuscripts and other scientific documents, and commonly receive training in Good Publication Practice.[23]

The findings of our study also suggest that overall compliance with CONSORT guidelines is lacking. Even with professional medical writing support, fewer than half of the articles reported at least 50% of studied CONSORT items completely. As well as authors, both peer reviewers and journal editors have responsibility for ensuring that articles adhere to reporting guidelines. However, peer reviewers often fail to notice important deficiencies in the reporting of RCTs.[18] In fact, peer reviewers may not understand the importance of checking the compliance of articles with CONSORT guidelines, possibly as a result of

insufficiently explicit instructions regarding their role.[24] From our own experience, checking an article for compliance with the full CONSORT checklist would take approximately 1 hour. We would recommend that this is a specialized task that could be undertaken by journal editors, or even by professional medical writers.

This study looked at the quality of published articles in a real-life situation. No limit was set on the year of article publication, although the study is limited by the date of inception of BioMed Central (2000). Because this was not a randomised study, the characteristics of the two groups of articles differ in some respects in addition to the involvement of medical writing support. The key differences between the two groups of articles were that those with declared medical writing support were almost exclusively sponsored by industry and were published more recently than those written without medical writing support. However, it seems unlikely that the results of this study can be attributed to these differences between the two groups of articles. Thus, in the subset of industry-funded trials, completeness of reporting was even more strongly associated with medical writing support. Furthermore, for each year of publication, the mean proportion of complete items was higher for articles with medical writing support than for those without. Articles with declared medical writing support were associated with a slightly longer overall acceptance time than articles without this support. One limitation of this assessment is that the measure of timeliness may not correspond to steps in the submission process that are the responsibility of the medical writer. The delay in overall acceptance was attributable to additional time taken for peer review and for the authors to respond to reviewers. Articles that declared medical writing support tended to describe larger trials than those without, and had more authors, suggesting that these articles may have reported more complex research and therefore taken longer to review or, possibly, underwent greater scrutiny by peer reviewers. Likewise, queries from peer reviewers may be more complicated for articles with medical writing support than for those without.

Our findings are based on the assumption that the enhanced quality of reporting observed can be attributed to medical writing support. It was not possible to discount the influence of some potential confounding factors, such as the expertise of the authors of the article (e.g. the presence of a statistician) or the quality of the clinical study report available. However, medical writers generally are more familiar than investigators with publication guidelines [12], and their role would normally include ensuring that the manuscript complies with journal submission criteria and compliance with reporting standards. It should also be noted that there are international guidelines regarding the content to be included in clinical study reports [25] and, in fact, these documents are usually written by medical writers.

The classification of articles in our study was based on the veracity of the acknowledgement of medical writing support. The importance of acknowledging medical writing support is stated in guidelines on Good Publication Practice and, according to the editorial policy of BioMed Central, medical writing support should be acknowledged explicitly.[14 26] Although we cannot rule out the possibility that some articles were written with undeclared writing support, this would tend to underestimate the true differences between the two groups. Finally, the articles that met the inclusion criteria for our study were from 74 different journals, but it remains to be seen whether our findings are applicable to journals other than those published by BioMed Central. The articles included in this study may not be representative of those published in journals that do not endorse the CONSORT checklist (i.e. the effect of medical writing support may be increased if authors do not receive guidance from the journal). Conversely, the effect of medical writing support may be reduced in journals that ensure compliance with CONSORT criteria.

A systematic review published in 2003 found that there was insufficient research to assess the effects of professional writing assistance on biomedical publishing.[27] Only one other study

has evaluated the association of declared medical writing support and the completeness of reporting.[20] This analysis was restricted to a single journal in which there were very few non-industry-sponsored studies and the overall completeness of reporting was high; although articles that declared professional medical writers were more likely to comply with the CONSORT criteria, the effect was small. A study of articles published in the *Dutch Journal of Medicine* found that editing for scientific content and written English, tasks that are often undertaken by medical writers, significantly improved the style and readability of manuscripts.[28] It has previously been suggested that, in addition to raising the standard of publications, professional medical writer involvement can speed up the publication process;[13] however, there is limited evidence to demonstrate the acceleration of manuscript acceptance with medical writing support,[29 30] and, in the current study, overall acceptance time was slightly longer in the group with medical writing support.

Clinical trials can help to advance the treatment of patients only if the methods and results are fully disclosed. The reporting of industry-sponsored studies appears to be improving over time,[31] and a recent study showed that industry-funded trials were more likely to comply with legal reporting obligations than trials funded by government or academic institutions.[32] Our results suggest that the enhanced reporting seen in industry-funded trials may be attributable to professional medical writing support. Even so, when only approximately half of research is published in full and many publications do not disclose important information, much research effort is wasted.[33] In fact, it has been proposed that professional medical writing support should be used to address the backlog of unreported clinical study results.[34] The results of the present study suggest that this support could also improve the quality of RCT reporting. Medical writing support is often funded by industry and, as a result, has sometimes attracted controversy.[35 36] There is no place for ghostwriting (i.e. the unacknowledged use of medical writers) in manuscript development.

According to the results of surveys, the overwhelming majority of authors (84–88%) valued the assistance provided by professional medical writers, in particular in editing manuscripts and ensuring conformity with reporting guidelines such as CONSORT.[37 38] Accordingly, the legitimate role that medical writers can play is acknowledged in guidelines on Good Publication Practice.[14]

Conclusions

There remains a need to improve the quality of reporting of clinical studies. The disclosure of important information regarding clinical studies, which is needed when determining the validity and generalisability of findings, may be enhanced with professional medical writing support.

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Contributors WTG and CCW were involved in the design, implementation, and analysis of the study, and in drafting the manuscript. SH, PF, RW, and EW were involved in the design and analysis of the study, and commented on the manuscript. KY conducted the statistical analysis of the study and commented on the manuscript. WTG is the guarantor of the study.

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Competing interests All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that: WTG, PF, RW, and CCW are medical communication professionals employed by Oxford PharmaGenesis. KY is a former employee of Oxford PharmaGenesis. PF, RW, and CCW are shareholders of Oxford PharmaGenesis. CCW holds shares in AstraZeneca and Shire Pharmaceuticals. SH is a member of the CONSORT group. EW is the owner of Sideview, which provides training and consultancy in medical writing, and has previously worked as a medical writer.

Data sharing The full dataset is available on request from the corresponding author (will.gattrell@pharmagenesis.com)

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Figure 1 Overview of the study design.

RCTs, randomised controlled trials.

The terms TIAB and PG allow searches to be specified based on title/abstract and article page number, respectively.

Figure 2 Differences in the reporting of CONSORT items between articles with and without acknowledged medical writing support.

CI, confidence interval; CONSORT, Consolidated Standards Of Reporting Trials; NA, not applicable.

*Relative risk could not be calculated for item 10 because all articles in the group without acknowledged medical writing support were assessed as having been incompletely described.

Supplementary figure 1 Year of article publication, stratified by medical writing support.

*Adjusted to number of articles per 12 months.

Supplementary figure 2 Mean proportion of complete items, stratified by year of publication and medical writing support.

The graph shows linear trend lines, which were calculated using Microsoft Excel.

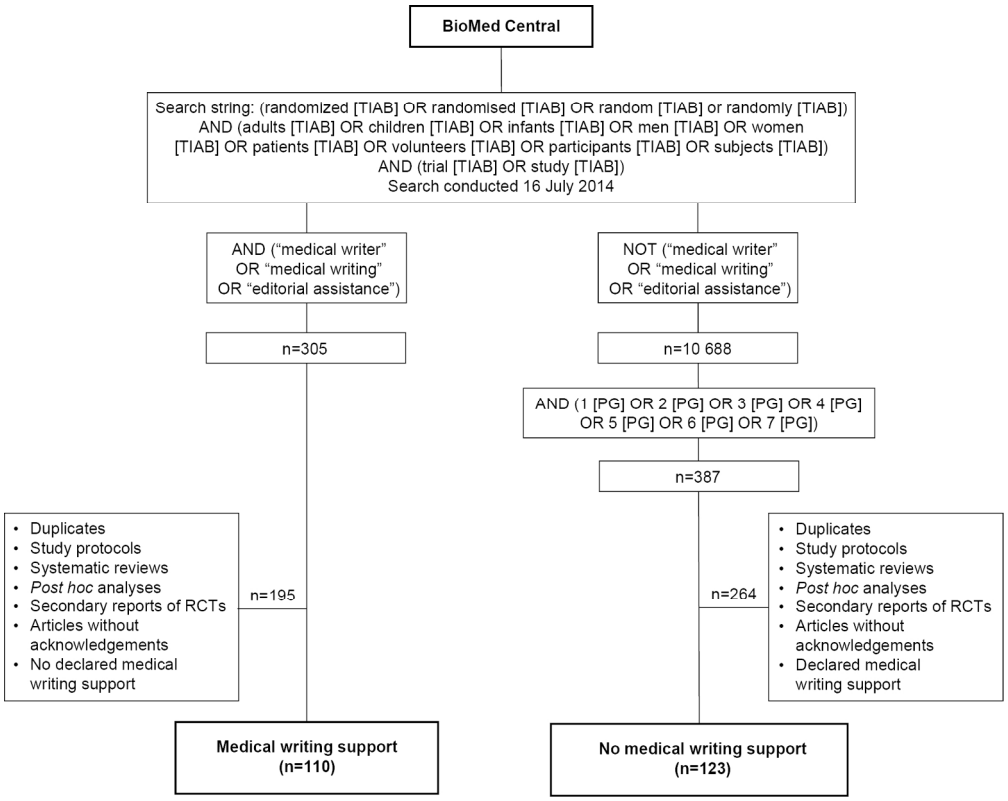


Figure 1 Overview of the study design.
RCTs, randomised controlled trials.
The terms TIAB and PG allow searches to be specified based on title/abstract and article page number, respectively.
174x137mm (300 x 300 DPI)

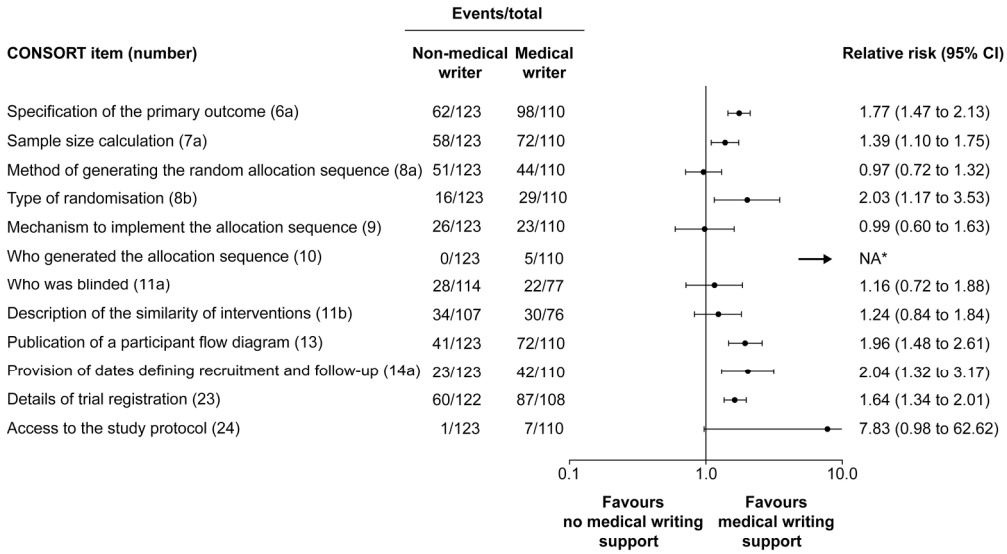


Figure 2 Differences in the reporting of CONSORT items between articles with and without acknowledged medical writing support.
CI, confidence interval; CONSORT, Consolidated Standards Of Reporting Trials; NA, not applicable.
*Relative risk could not be calculated for item 10 because all articles in the group without acknowledged medical writing support were assessed as having been incompletely described.
96x52mm (600 x 600 DPI)

Supplementary table 1 Criteria used for assessing the completeness of reporting, based on the 2010 CONSORT checklist

Definitions used to assess the completeness of reporting (CONSORT item and number)
Specification of the primary outcome (6a) *Complete:* primary/main outcome defined and fully described *Incomplete:* outcome present, but not defined as such
Sample size calculation (7a) *Complete:* method of power calculation included *Incomplete:* planned sample size mentioned but values or methods not reported
Method of generating random allocation sequence (8a) *Complete:* specific method of randomisation given (e.g. random number table) *Incomplete:* non-specific method given (e.g. "automated randomisation system")
Type of randomisation (8b) *Complete:* full details of randomisation given *Incomplete:* type of randomisation described but no details given
Mechanism to implement allocation sequence (9) *Complete:* both the mechanism used and how the allocation was concealed were present *Incomplete*: either the mechanism used or how the allocation was concealed were described
Who generated the allocation sequence (10) *Complete*: description of who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions *Incomplete*: one or two of these described

Definitions used to assess the completeness of reporting (CONSORT item and number)
Who was blinded (11a)
Complete: blinding status of all groups (participants/investigators/assessors) defined
Incomplete: blinding status of one or more groups described
Absent: stated as "single-blind" or "double-blind" only
NA: open-label study
Description of the similarity of interventions (11b)
Complete: relevant similarities described (appearance/taste/smell/volume/method of administration)
Incomplete: described only as 'identical', 'matching' or 'corresponding' etc.
NA: treatment defined as open label or interventions stated as too dissimilar to blind
Publication of a participant flow diagram (13)
Complete: diagram showed number of patients enrolled, numbers excluded and lost to follow-up, and reasons for exclusion or loss to follow-up
Incomplete: diagram included patient flow and numbers enrolled but was missing some information
Dates defining recruitment and follow-up periods (14a)
Complete: period of study/recruitment and follow-up period fully defined
Incomplete: only one of the above periods defined
Details of trial registration (23)
Complete: registration number stated in text
NA: study conducted before the International Committee of Medical Journal Editors recommendation that clinical trials should be registered at or before the time of first patient enrolment
Access to the study protocol (24)
Complete: protocol number and location/registry stated

For the full list of items on the CONSORT checklist, see: http://www.consort-statement.org/

CONSORT, Consolidated Standards Of Reporting Trials; NA, not applicable.

Supplementary table 2

	Proportion of articles correctly reported				
	≥50%	≥66.6%	≥75%	≥90%	100%
No medical writing support	21.1%	4.9%	1.6%	0	0
Medical writing support	39.1%	18.2%	9.1%	0.9%	0

Supplementary table 3 Time to complete different stages of article processing

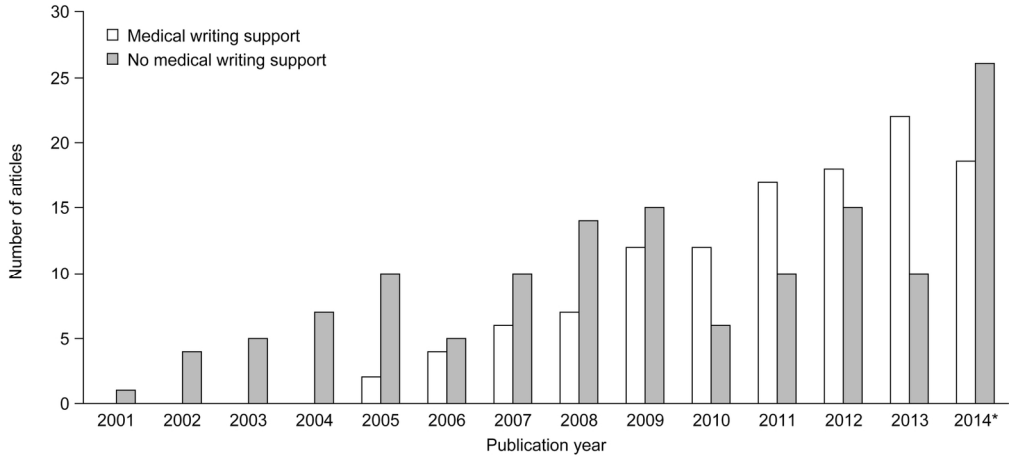
Duration, days	Medical writing support (n=55)	No medical writing support (n=64)
Peer review	87 (55–122)	55 (35.5–86.75)
Responding to reviewers	60 (35–83)	32 (17–58.25)
Editorial acceptance	49 (23–96)	50 (29.75–98.75)
Submission to editorial acceptance	206 (164–264)	162.5 (104.25–217.5)

Data are presented as median (interquartile range).

Supplementary table 4 Time to complete different stages of article processing (industry-funded articles only)

Duration, days	**Medical writing support (n=55)**	**No medical writing support (n=18)**
Peer review	87 (55–122)	50.5 (37.75–74.25)
Responding to reviewers	60 (35–83)	28 (13–67.75)
Editorial acceptance	49 (23–96)	50 (39.5–113.25)
Submission to editorial acceptance	206 (164–264)	161 (103.5–270.25)

Data are presented as median (interquartile range).



Supplementary figure 1 Year of article publication, stratified by medical writing support.
*Adjusted to number of articles per 12 months.
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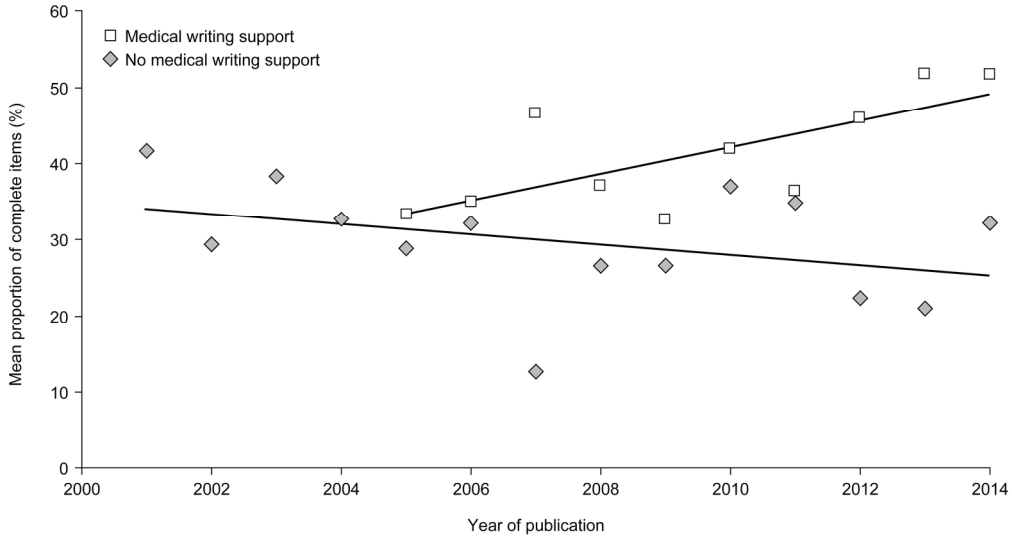

Supplementary figure 2 Mean proportion of complete items, stratified by year of publication and medical writing support.

The graph shows linear trend lines, which were calculated using Microsoft Excel.
91x48mm (600 x 600 DPI)

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page number
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2–3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7–8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	7–8
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8–9
Bias	9	Describe any efforts to address potential sources of bias	9
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9
		(*b*) Describe any methods used to examine subgroups and interactions	9
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, explain how loss to follow-up was addressed	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11 and Table 1
		(b) Indicate number of participants with missing data for each variable of interest	11–13
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over time	12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted	11–13

		estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	13–14
Discussion			
Key results	18	Summarise key results with reference to study objectives	16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16–18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16–19
Generalisability	21	Discuss the generalisability (external validity) of the study results	16–19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.