BACKGROUND

- The complete reporting of clinical trial findings is at the heart of evidence-based medicine, but suboptimal reporting is widespread.¹
- Clinicians may choose to work with professional medical writers to help them to prepare their findings for publication.
- The role of medical writer support is recognized in guidelines on Good Publication Practice.²
- The aim of this study was to examine the relationship between professional medical writer support in manuscript preparation and:
  - quality of reporting of clinical study results
  - quality of written English
  - speed of acceptance.

RESEARCH DESIGN AND METHODS

- Articles describing the results of randomized controlled trials (RCTs) were identified in BioMed Central journals (Figure 1).¹ ²
  - A full-text search identified those with acknowledged medical writer support (MW) – The control group without acknowledged medical writer support (non-MW) comprised the remainder of articles, reduced in an unbiased manner to a manageable size by selecting those beginning with page numbers 1–7 inclusive.
- Duplicates, reviews, post hoc analyses and study protocols were excluded.
- The quality of reporting of RCTs was assessed using the Consolidated Standards of Reporting Trials (CONSORT) checklist, focusing on items previously shown to be poorly reported.¹ ²

Data collection

- Reporting of CONSORT items was assessed independently by two reviewers who were blinded to the study objectives. In cases of discrepancy, a third reviewer adjudicated. Items were classified as one of the following:
  - completely described
  - incompletely described
  - absent
  - not applicable.

RESULTS

- Characteristics of the study groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>MWArticles</th>
<th>Non-MWArticles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean number of patients</td>
<td>159</td>
<td>17.9</td>
</tr>
<tr>
<td>Type of randomization</td>
<td>Industry-funded</td>
<td>Non-policy-funded</td>
</tr>
<tr>
<td>Industry-funded MW articles</td>
<td>50%</td>
<td>29.9%</td>
</tr>
<tr>
<td>Industry-funded non-MW articles</td>
<td>50%</td>
<td>48.9%</td>
</tr>
<tr>
<td>Industry-funded non-MW articles</td>
<td>50%</td>
<td>21.1%</td>
</tr>
</tbody>
</table>

Adherence to CONSORT items

- Most CONSORT items had a significantly higher rate of complete reporting in MW articles than in non-MW articles (Figure 2).

DISCUSSION

- We used robust methodology and objective measures to assess the reporting of the results of RCTs. All eligible MW articles in BioMed Central journals were included.
- Although the results obtained may in part reflect the characteristics of MW articles, and an observational study such as this cannot establish cause and effect, there are sound reasons to believe that the involvement of professional medical writers improves the quality of articles.
- A limitation is that the study relied on medical writer support being declared; however, according to BioMed Central editorial policy, medical writer support should be acknowledged explicitly. Any undisclosed medical writing support will have tended to understate the effect observed.

CONCLUSIONS

- Professional medical writer support was associated with higher quality RCT reporting, but a longer time from article submission to acceptance.
- The quality of clinical trial reporting may be enhanced with professional medical writer support.

Acknowledgments

The authors thank Stephen Langford for development of the article ratings and for data extraction, and Kate Young for conducting the statistical analyses.

References


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

Figure 3. Completeness of reporting of CONSORT items.

Figure 4. Quality of written English, as assessed by peer reviewers.

About BioMed Central journals

- BioMed Central publishes over 290 peer-reviewed, open-access journals.
- To date, approximately 250 000 articles have been published.
- For journals in the BMC series (e.g. BMC Medicine), pre-publication history, including the dates of submission and acceptance, and peer reviewers’ assessments of the quality of written English are available.

The recorded data were dichotomized as complete versus incomplete or absent for each CONSORT item, and the relative risk was calculated.

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

Note: n = number of articles; OR = or; CI = confidence interval; CONSORT = Consolidated Standards of Reporting Trials; RCT = randomized controlled trial.

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