

# Professional medical writing support improves the quality of reporting of randomized controlled trials

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## BACKGROUND

- ISMPP acknowledges the skills and training of professional medical writers and their role in the timely development of clear and concise manuscripts.<sup>1</sup>
- EMWA asserts that involving a professional medical writer can “raise the standard of publications and accelerate the writing and publication process”;<sup>2</sup> however, there is limited evidence to support this view.<sup>3</sup>
- 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).
  - 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.
- Reviews, *post hoc* analyses, study protocols and RCTs of non-pharmacological interventions 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.<sup>4,5</sup>

### 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.

### About BioMed Central journals

- BioMed Central publishes 277 peer-reviewed, open-access journals.
- To date, 236 735 articles have been published.
- For journals in the BMC series (e.g. *BMC Medicine*), pre-publication history is available, including the dates of submission and acceptance, and peer reviewers' assessments of the quality of written English.
  - This is rated as one of the following:
    - acceptable
    - needs some language corrections before being published
    - not suitable for publication unless extensively revised.

Figure 1. Overview of the study design.

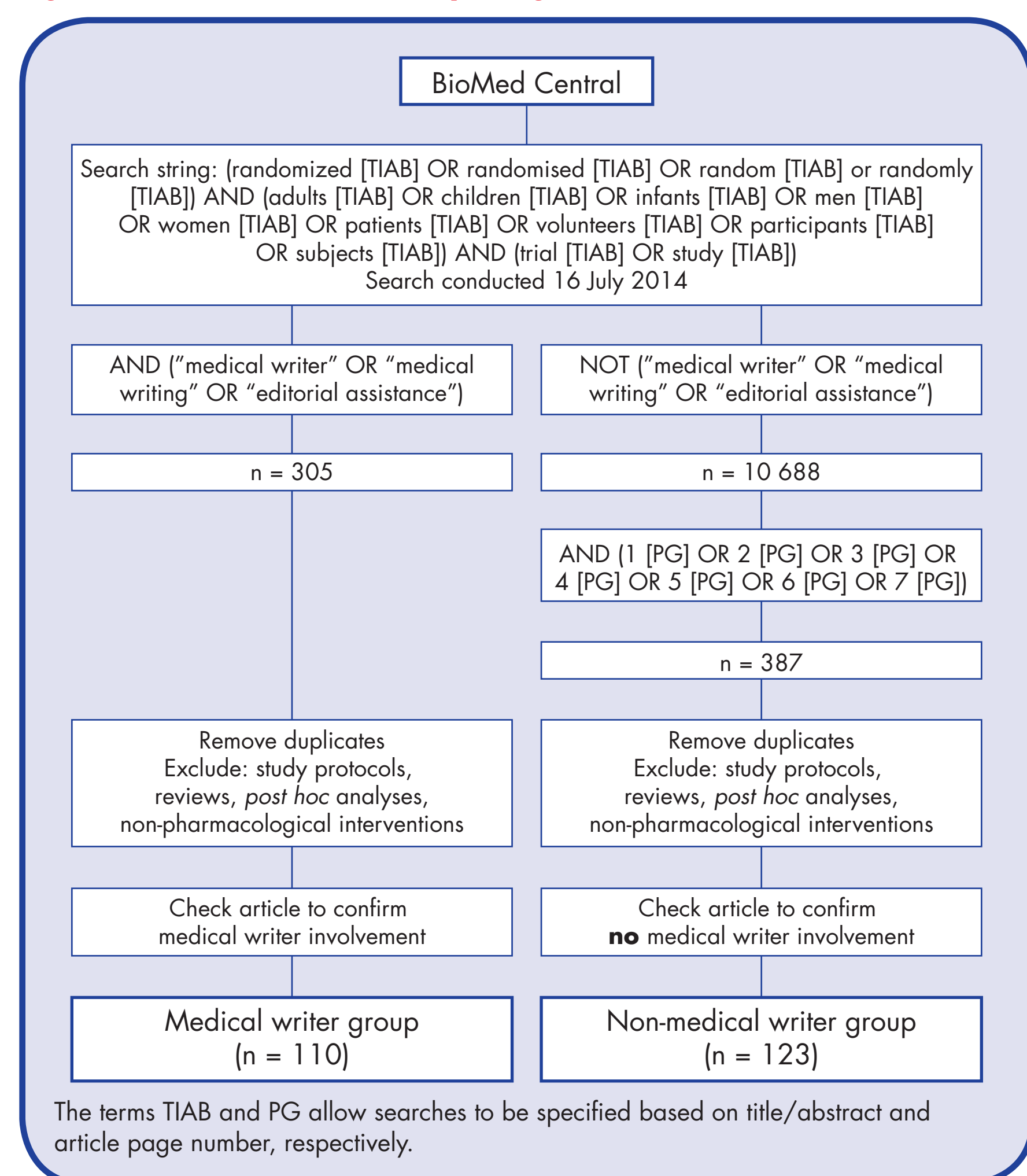


Figure 2. Differences in the complete reporting of CONSORT items between articles with and without acknowledged medical writer support.

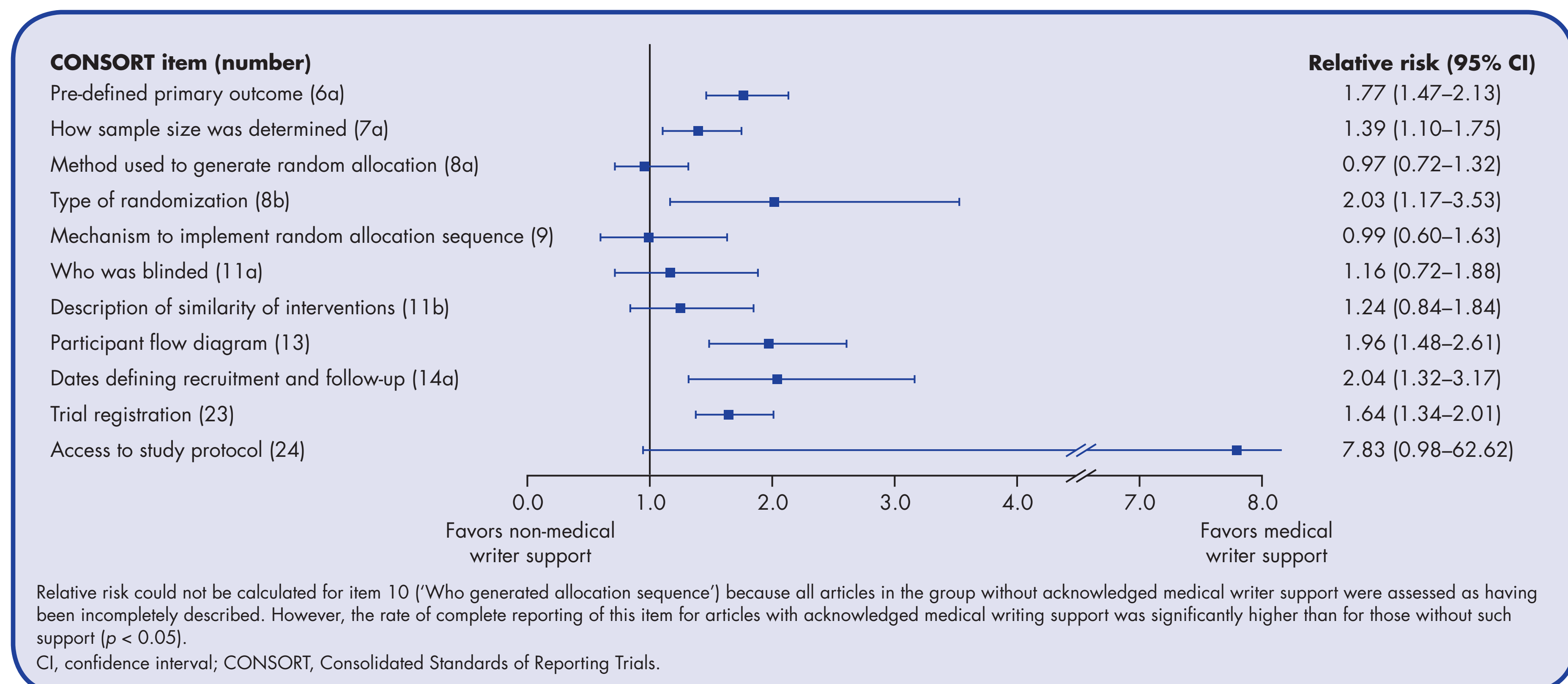
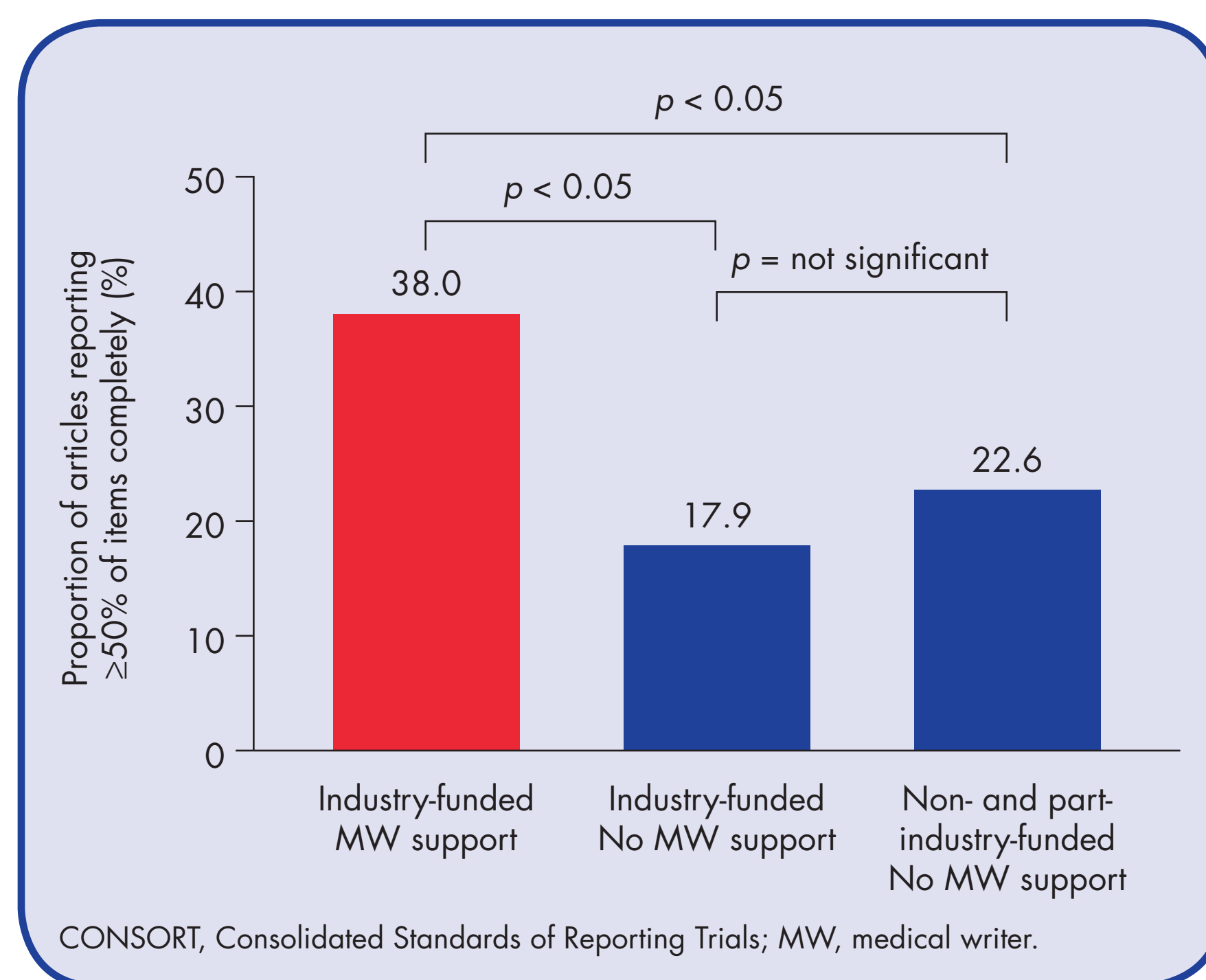


Figure 3. Completeness of reporting of CONSORT items.



- The recorded data were dichotomized as complete versus incomplete or absent for each CONSORT item and the relative risk was calculated.
- Article characteristics (such as mean number of authors), quality of written English and speed of acceptance were compared between the two study groups using the Mann–Whitney U test, Fisher's exact test or  $\chi^2$  test, as applicable.

## RESULTS

### Characteristics of the study groups

- We identified 110 MW articles and 123 non-MW articles (Figure 1).
- There were statistically significant differences between the characteristics of the two groups ( $p < 0.001$ ):
  - MW articles were industry (98.2%) or part-industry funded (1.8%); non-MW articles were industry (31.7%), part-industry (18.7%) or non-industry funded (49.6%)
  - the median number of patients in the RCTs was 159 for MW articles and 43 for non-MW articles
  - the mean number of authors was 7.5 for MW articles and 6.4 for non-MW articles.

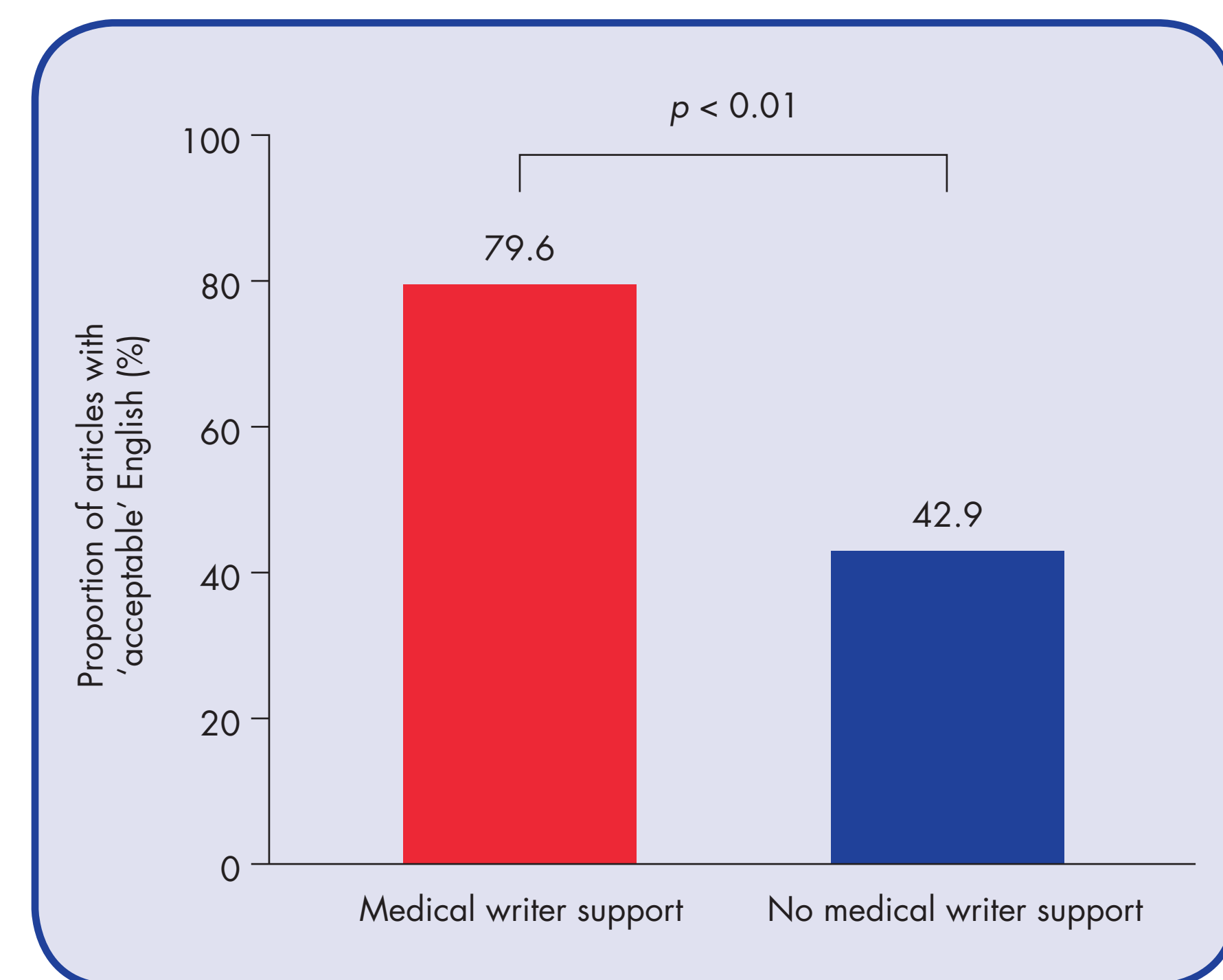
### Adherence to CONSORT items

- Most CONSORT items had a significantly higher rate of complete reporting in MW articles than in non-MW articles (Figure 2).
- MW articles were nearly twice as likely as non-MW articles to report at least 50% of studied items completely (39.1% vs 21.1% of articles;  $p < 0.05$ ).
- Industry-funded MW articles were more than twice as likely as industry-funded non-MW articles to report at least 50% of studied items completely (38.0% vs 17.9%,  $p < 0.05$ ; Figure 3). For non-MW articles, funding source had no significant effect on the quality of reporting.

### Quality of written English and speed of acceptance

- MW articles were significantly more frequently rated by peer reviewers as having acceptable written English than were non-MW articles (79.6% vs 42.9%;  $p < 0.01$ ; Figure 4).
- Median time from submission to acceptance was significantly longer for MW articles than for non-MW articles (167.0 vs 136.0 days;  $p < 0.01$ ).

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



## 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 writing support should be acknowledged explicitly.<sup>6</sup> Given the large number of non-MW articles, the proportion that were in fact written with the undeclared involvement of a medical writer is likely to be low.

## CONCLUSIONS

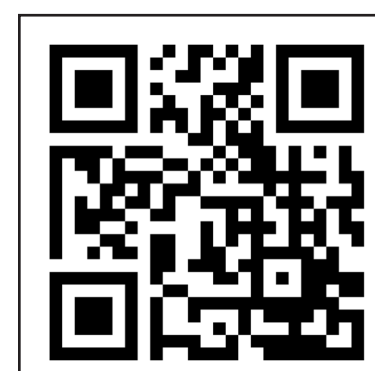
- Professional medical writing support was associated with higher-quality reporting of RCT results than articles without such support.
- ISMPP, with its mission to support the educational needs of medical publication professionals,<sup>1</sup> can play an important role in achieving this.

### Disclosures

This study was funded by Oxford PharmaGenesis. W Gattrell, K Young, P Farrow, R White and C Winchester are medical communication professionals employed by Oxford PharmaGenesis. S Lang is a former employee of Oxford PharmaGenesis. E Wager is the owner of Sideview, which provides training and consultancy in medical writing.

### References

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